



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

FEB 28 2003

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

Mr. John Bickel
Vice President
Statlab Medical Product
P.O. Box 1155
Lewisville, TX 75067

Ref. No. 03-0038

Dear Mr. Bickel:

This is in response to your January 30, 2003 letter regarding the classification of formaldehyde under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you ask whether a solution of 4% formaldehyde mixed with non-hazardous materials shipped in 20 ml, 30 ml, 45 ml, 60 ml, and 120 ml vials by aircraft are subject to the HMR.

Based on subsequent information you provided to this Office, it is our opinion that your products are not subject to the requirements of the HMR. Generally, solutions of less than 10% formaldehyde mixed with non-hazardous materials do not meet the definition of a Class 9 hazardous material and, provided they do not meet any other hazard class, are not subject to the HMR. However, as provided by § 173.22 of the HMR, it is the shipper's responsibility to properly class a hazardous material. Generally, manufacturers have the knowledge to properly class the materials and products they produce. However, in some situations, it may be necessary to enlist an outside laboratory to assist in the classification process as testing may have to be conducted to see how a product compares to the criteria for the various hazard classes.

I hope this satisfies your request.

Sincerely,

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



030038

173.22



Betts
\$173.22, \$173.24
Shipper's Responsibility
Small Quantity
03-0038
106 Hillside Dr.
Lewisville, TX 75057

Phone 97-436-1010 x20
Fax 972-436-1369
Email jdbickel@statlab.com

1/30/03

Mr. Edward Mazzulo
Director of Office of Hazardous Materials Standards
Department of Transportation
Room 8422, 7th. St SW
Washington, DC 20590

by fax: 202-366-3012

Dear Mr. Mazzulo:

I am requesting a revised letter of interpretation from you office regarding the transportation of small quantities of formalin solution. Please reference your letter (01-0184) dated 9/4/01 and the original inquiry that is attached.

It is my opinion that Mr. Gale agreed that for the specified material (4% formaldehyde and balance being water and other non-hazardous materials aka. 10% formalin solution) in unit volumes* of 13mL that these would not be a regulated material when shipped by air. If this is correct my follow up question deals with how to treat larger volumes of this same material in the same concentrations. Specifically, there are additional sizes of these units produced and shipped by air. They include the following volumes of material: 20mL, 30mL, 45mL, 60mL and a 120mL.

It is my view that 10% formalin in any of the above referenced volumes would not be regulated when shipped by air. Can you please confirm this understanding or state your objections? I would very much appreciate your timely response to this matter.

Sincerely,

John Bickel, VP

*all referenced units are packaged in plastic screw top vials which have passed the 95kPa pressure test.



106 Hillside Dr.
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Phone 97-436-1010 x20
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7/16/01

Mr. Edward Mazzulo
Director of Office of Hazardous Materials Standards
Department of Transportation
Room 8422, 7th. St SW
Washington, DC 20590

by fax: 202-366-3012

Dear Mr. Mazzulo:

I am requesting a revised letter of interpretation from your office regarding the transportation of small quantities of formalin solution. I understand this issue has been addressed by your office previously (6/95 letter to J.G. McKay with SAF-T-PAK) but have additional information which may be of interest.

By way of clarification formalin solution (aka 10% formalin) typically consists of 3.7-4% of actual formaldehyde with the balance being water and other non-hazardous materials. Formalin solution is generally packaged in small, screw-top plastic vials of various sizes for diagnostic purposes. These vials are filled to 1/2 capacity, the smallest of which (and most popular) contains 13mL of formalin. I estimate that roughly 70 million of these vials are distributed to laboratories in the US, most of which are shipped unregulated by air. It is quite clear that formalin solution in this dilution meets neither the definition of UN2209 or UN1198. It has instead been casually classed as UN3335 which leaves it subject to debate. Insofar as these formalin vials are generally shipped unregulated by laboratories across the country I can't help but conclude that the collective opinion is that formalin solution does not meet any definition of hazardous material and is regarded accordingly. To put another way, if this conclusion were inaccurate the economic and administrative impact would be tremendous to these laboratories.

So on the one hand there exists the letter of interpretation from your office suggesting class 9 status and the other being the collective opinion across the country which departs from this interpretation. I believe this collective opinion is based on the notion that formalin solution at the 3.7-4% range does not rise to the level of being a substance "which has narcotic, noxious or other properties such that, in the event of leakage or spillage on an aircraft extreme annoyance or discomfort could be caused to crew members so as to prevent the correct performance of assigned duties." This is particularly so given the very small volumes of material contained in these vials. (note: the actual formaldehyde content per 13mL vial is less than .52mL)

Accordingly, it is my opinion that 10% formalin solution does not meet the definition of a hazard and can ship unregulated by air as it does by ground. Can you please confirm this understanding or state your objections? I would very much appreciate your timely response to this matter.

Sincerely,

John Bickel, VP



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SEP - 4 2001

Mr. John Bickel
Vice President
Statlab Medical Product
P.O. Box 1155
Lewisville, TX 75067

Ref. No. 01-0184

Dear Mr. Bickel:

This is in response to your July 16, 2001 letter and subsequent telephone conversation with Eric Nelson of my staff regarding the classification of formaldehyde under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically, you cite a June 6, 1995 letter sent from this Office to J. G. McKay, and ask if a solution of 3.7 to 4% formaldehyde mixed with non-hazardous materials shipped in 13 ml vials by aircraft are subject to the HMR.

Based on subsequent information you provided to this Office, it is our opinion that your products are not subject to the requirements of the HMR. The letter you refer to addresses 10% formaldehyde solutions, which meet the definition of a Class 9 hazardous material. Generally, solutions of less than 10% formaldehyde mixed with non-hazardous materials do not meet the definition of a Class 9 hazardous material and, provided they do not meet any other hazard class, are not subject to the HMR. However, as provided by § 173.22 of the HMR, it is the shipper's responsibility to properly class a hazardous material. Generally, manufacturers have the knowledge to properly class the materials and products they produce, although it may be necessary to enlist an outside laboratory to assist in classification process, as testing may have to be conducted to see how a product compares to the criteria for various hazard classes.

I hope this satisfies your request.

Sincerely,

John A. Gale
Transportation Regulations Specialist
Office of Hazardous Materials Standards