

U.S. Department of Transportation

1200 New Jersey Ave, SE Washington, D.C. 20590

## Pipeline and Hazardous Materials Safety Administration MAR 0 3 2011

Mr. George Kerchner Wiley Rein LLP 1776 K Street, NW Washington, DC 20006

Ref. No. 10-0169

Dear Mr. Kerchner:

This responds to your letter regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) to your client's medical devices that contain small amounts of hazardous materials. Specifically, you ask whether such devices (copper pipe) used as part of a process to analyze human blood are subject to the HMR when they may include trace amounts of copper azide in a mixture of salts (copper phosphate, copper oxide, and copper hydroxide). The mixture is formed in the copper pipe after flushing it with an aqueous buffer solution containing sodium azide, sodium phosphate, sodium biphosphate, and sodium chloride. Your client intends to ship approximately ten pieces of the copper pipe submerged in the buffer solution and further packaged within small, individual bottles. It is your understanding that copper azide in its pure form is a Class 1 (explosive) normally forbidden for transportation in commerce. You also believe that any residual copper azide that may be on the copper pipe will not be pure copper azide, nor will it exhibit any explosive properties.

Under § 173.22, it is a shipper's responsibility to properly classify and describe a hazardous material. This Office does not normally perform that function. However, it is the opinion of this Office that the trace amounts of copper azide that may be present in your client's copper pipe described above is not regulated as a Class 1 explosive. We also agree with your assessment that it is not in a form or quantity that poses an unreasonable risk to health and safety or property in transportation and, therefore, is not subject to the HMR.

I trust this satisfies your inquiry. Please contact us if we can be of further assistance.

Sincerely,

T. Glenn Foster

Chief, Regulatory Review and Reinvention Branch

Standards and Rulemaking Division

7 Alenn Feet



1776 K STREET NW
WASHINGTON, DC 20006
PHONE 202.719.7000
FAX 202.719.7049

July 28, 2010

7925 JONES BRANCH DRIVE McLEAN, VA 22102 PHONE 703.905.2800

FAX 703.905.2800

www.wileyrein.com

Stevens \$172.101 \$173.56 Explosive 10-0169

> George Kerchner 202.719.4109 gkerchner@wileyrein.com

Office of Hazardous Materials Standards
Pipeline and Hazardous Materials Safety Administration
U.S. Department of Transportation
1200 New Jersey Avenue, SE
Washington, D.C. 20590

Re: Classification of Copper Pipe Possibly Containing Copper Azide in a Mixture of Salts

I am writing to request a written confirmation from the Pipeline and Hazardous Materials Safety Administration (PHMSA) regarding the classification of small amounts of copper azide that may be present on copper tubes used in medical labs. We spoke to Dr. Charles Ke of your office regarding this issue several weeks ago.

Sodium azide-containing aqueous buffer solution often is used in a medical device to analyze human blood. The buffer solution also contains sodium phosphate, sodium biphosphate, and sodium chloride. The buffer solution is flushed down through a copper pipe after usage. Because the buffer solution contains sodium azide and other salts, there is a small possibility of formation of copper azide along with copper phosphate, copper oxide, and copper hydroxide when the buffer solution flows through the copper pipe while flushing. In fact, possibility of formation of copper phosphate is higher than copper azide as copper phosphate is much less soluble than copper azide in water. These salts are expected to deposit on the inner lining of the copper pipe. In order to confirm or negate the presence of copper azide, estimate the amount of copper azide per unit area of the pipe, and conduct a hazard assessment of the copper azide amount in the pipe, it will be necessary to ship small pieces (approximately 0.5-inch-diameter and 1.0-inch-long in size) of the copper pipe for analysis. Our client is planning to ship approximately 10 pieces of this copper pipe.

We recognize that copper azide may be classified as a Class 1 Explosive hazardous material when shipped in its purest form. However, any residual copper azide that may be on the copper pipe as described above will not be pure copper azide or have the properties of a Class 1 Explosive.

Each piece of copper pipe will be packaged in small, separate bottles and submerged in the buffer solution inside the bottles. We believe the copper azide that may be present in very small amounts on the copper tube is not in a form or quantity that poses an unreasonable risk to health and safety or property in transport.



July 28, 2010 Page 2

Therefore, it is our view that the pieces of copper tube are not subject to the hazardous materials regulations.

We would appreciate written confirmation from PHMSA that our classification of these materials is consistent with the hazardous materials regulations.

Thank you for your assistance.

Sincerely,

George Kerchner

George Kerchner