



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

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

NOV 13 2002

James L. Prescott, PhD  
UroCor  
Division of DIANON Systems  
840 Research Parkway  
Oklahoma City, Oklahoma 73104

Ref. No. 02-0187

Dear Dr. Prescott:

This responds to your letter dated July 11, 2002 regarding the requirements for shipping aqueous solutions of alcohol under the Hazardous Materials Regulations (HMR, 49 CFR Parts 171-180) as they apply to a "fixative" containing approximately 20% ethanol and 75-77% water, used in the diagnosis and treatment of cancer and genetic diseases. Your provided information, as follows:

When Dianon's clients ship a mixture of the fixative and urine sample to Dianon for diagnosis, the final concentrations of the mixed fixative and urine sample are 12.5 mM 3-[N-Morpholino]-2-hydroxypropanesulfonic acid and 20% ethanol. Since the major component of urine is water (constituting about 90-95% of the volume of urine), the percentage of water in the mixture of fixative and urine sample is 75-77%. Further, the urine sample is a diagnostic specimen as defined in § 173.134(a)(2), and excepted from the HMR in accordance with § 173.134(b)(1)(ii).

Specifically, you asked for confirmation that your understanding is correct that this mixed fixative and urine sample shipped by physicians back to Dianon for diagnosis complies with the aqueous solution exception in § 173.150(e) and is not subject to the HMR.

Your understanding is correct. As provided in § 173.150(e), an aqueous solution containing no less than 50% water and 24% or less alcohol by volume and no other hazardous material is not subject to the HMR. The aqueous solution, described in your letter, containing 75-77% water and 20% alcohol (ethanol) by volume and no other hazardous material (used as a fixative to preserve cells in the urine sample during transportation) satisfies the exception criteria and is not subject to the HMR. Currently, the mixture of the fixative and urine sample is not subject to the HMR when it is shipped as a "diagnostic specimen", as specified in § 173.134, for purposes of diagnosis.

On August 14, 2002, a final rule [67 FR 53118] was issued revising the exception for diagnostic specimens and biological products, and on August 27, 2002, a correction to the final rule [67 FR 54967] was issued correcting the effective date. Therefore, effective February 14, 2003, the current exception for diagnostic specimens will no longer apply. Packaging and marking requirements



020187

173.150

applicable to diagnostic specimens thought to contain a Risk Group 2 or 3 infectious material are found in a new § 173.199. Diagnostic specimens thought to contain a Risk Group 4 material are regulated as Division 6.2 materials and must meet packaging requirements in § 173.196 and all labeling, marking, and shipping documentation requirements. An exception from all regulation for diagnostic specimens transported by private or contract motor carriers in dedicated vehicles is found in § 173.134(b)(6). Diagnostic specimens that do not contain a pathogen or in which the pathogen has been inactivated or neutralized so that it cannot cause disease are not regulated as infectious substances; however, they may be regulated as hazardous material if the neutralizing agent meets the definition of another hazard class. The final rule and correction document (Docket No. HM-226) are available on our web site at the following URL: <http://hazmat.dot.gov>.

I hope this satisfies your inquiry. If we can be of further assistance, please contact us.

Sincerely,



Delmer F. Billings  
Chief, Standards Development  
Office of Hazardous Materials Standards



A Division of DIANON Systems

July 11, 2002

Mr. Edward T. Mazzullo  
Director, Office of Hazardous Materials Standards (DHM-10)  
Research and Special Programs Administration ("RSPA")  
U.S. Department of Transportation  
400 7<sup>th</sup> Street, SW  
Washington, DC 20590-0001  
Facsimile (202) 366-3012

Engrum  
§ 173.150  
Exceptions  
02-0187

Dear Mr. Mazzullo:

Dianon Systems, Inc. ("Dianon") is one of this country's largest laboratories providing pathology and cytology services. Through its work, Dianon aids physicians in the diagnosis and treatment of cancer and genetic diseases. Dianon receives thousands of tissue and body samples each day from physicians, and counts among its clients 5,000 of the country's 7,500 urologists.

Cytological analysis of the cells found in voided urine is routinely used to detect and monitor bladder cancer. To preserve the cells in the urine during transportation, a pH-buffered water-ethanol solution is added to the urine as a fixative. As part of its services, Dianon provides this fixative to physicians and receives from the physicians a mixture of the fixative and voided urine.

The starting concentrations of the fixative are 25 mM 3-[N-Morpholino]-2-hydroxypropanesulfonic acid (MOPSO, CAS#68399-77-9), pH 6.5, 40% (v/v) ethanol (CAS# 64-17-5), a flammable liquid. The remaining 59% of the volume is water.

Physicians are instructed to gently mix each urine sample with a volume of the fixative equal to the volume of the urine and ship it back to Dianon for diagnostic services. The final concentrations of the mixed fixative and urine sample are 12.5 mM MOPSO, and 20% ethanol. Since the major component of urine is water (constituting about 90-95% of the volume of urine), the percentage of water in the mixture of fixative and urine sample is 75-77%.

When shipped from Dianon to the Dianon's clients, the fixative is a hazardous material and treated as such for transportation purposes. However, Dianon believes that, when Dianon's clients ship a mixture of the fixative and urine sample back to Dianon, the material satisfies the aqueous solution exemption in Hazardous Materials Regulations ("HMR") § 173.150(e).

The aqueous solution exemption applies to aqueous solutions "containing 24% or less alcohol by volume and no other hazardous material." HMR § 173.150(e). Material

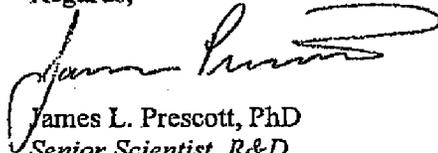
satisfying these conditions "[m]ay be reclassified as a combustible liquid," and is not subject to the HMR "if it contains no less than 50% water." HMR § 173.150(e)(1)-(2).

The mixed solution contains only 20% ethanol, which is less than the 24% called for in HMR § 173.150(e). The material contains approximately 75-77% of water, which is above the 50% required by HMR § 173.150(e)(2). Further, at the time the material is shipped to Dianon by Dianon's clients, there is "no other hazardous material" in the shipment since the urine sample is a diagnostic specimen exempt from the regulations under HMR § HMR 173.134(a)(2) and (b)(ii).'

Through this letter, Dianon asks RSPA to confirm Dianon's belief that the shipment of the mixed fixative and urine sample, when shipped by Dianon's clients to Dianon as outlined in this letter according to Dianon's procedures, complies with HMR § 173.150(e), and therefore is not subject to the remaining provisions of the HMR.

Thank you for your assistance and we look forward to hearing from you. If you need any further information regarding our products please do not hesitate to contact me at (405)290-4228.

Regards,



James L. Prescott, PhD  
Senior Scientist, R&D  
UroCor, A Division of Dianon Systems

The urine sample is human excreta being shipped for diagnostic purposes, HMR § 173.134(a)(2), and is therefore exempt if packaged in such a way that no other material subject to the HMR is included. HMR § 173.134(b).