



U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

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

OCT 14 2014

Nicholas Pagerly
Quest Diagnostics
159 Air Museum Dr.
Reading, PA 19605

Ref. No.: 14-0070

Dear Mr. Pagerly:

This responds to your March 26, 2014 letter requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to limited quantities of ethyl alcohol. In your letter, you state that your company provides medical laboratory testing to the public and medical professions worldwide. You note that a recently published final rule entitled "Hazardous Materials: Incorporation of Certain Special Permits and Competent Authorities into Regulations" [Docket No. PHMSA 2011-0158 (HM-233C)], published on March 18, 2014 [79 FR 15033] revised the provisions for limited quantities of retail products containing ethyl alcohol. You ask how the Pipeline and Hazardous Materials Safety Administration (PHMSA) defines "medical screening solutions" as it pertains to the exception for limited quantities of ethyl alcohol provided in § 173.150(g).

PHMSA interprets medical screening solutions to mean any solution used to perform part or all of a screening test designed to identify an unrecognized disease in an individual or population that does not display any signs or symptoms of a disease. As this term is used in § 173.150(g), medical screening solutions means one or more solutions or concentrates sold as a retail product that contains 70 percent or less "UN 1170, Ethyl alcohol, 3 (flammable liquid), PG II or III," by volume for liquids or by weight for solids, that are placed in packagings with a liquid or solid material in conformance with the requirements prescribed in § 173.150(g).

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

Andrews
§ 173.50(g)
Definitions
14-0070



March 26, 2014

U.S. DOT
PHMSA Office of Hazardous Materials Standards
Attn: PHH-10
East Building
1200 New Jersey Avenue, SE.
Washington, DC 20590-0001

Dear Sirs,

PHMSA recently released a final rule (HM-233C) which describes changes to 49 CFR 173.50. The specific change to 49 CFR 173.50 states:

(g) Limited quantities of retail products containing ethyl alcohol. (1) Beverages, food, cosmetics and medicines, medical screening solutions, and concentrates sold as retail products containing ethyl alcohol classed as a flammable liquid or flammable solid containing not more than 70% ethyl alcohol by volume for liquids, by weight for solids are excepted from the HMR provided that:

(i) For non-glass inner packagings:

(A) The volume does not exceed 16 fluid ounces in capacity for liquids; or

(2) Beverages, food, cosmetics and medicines, medical screening solutions, and concentrates sold as retail products containing ethyl alcohol classed as a flammable liquid or flammable solid containing more than 70% ethyl alcohol by volume, by weight for solids are excepted from the HMR provided that:

(3) For transportation by passenger or cargo aircraft, no outer package may be transported which contains an inner packaging exceeding: (i) 16 fluid ounces of flammable liquid, or (ii) 1 pound of solids containing flammable liquid.

Quest Diagnostics is an organization that provides medical laboratory testing to the public and medical professionals worldwide. In this capacity, we transport by commercial and private air carrier, tissue and other types of specimens that are fixed in solutions that contain ethyl alcohol. Specifically, we are most interested in the exemption regarding medical screening solutions that contain ethyl alcohol. We are of the opinion that these solutions would qualify as "medical screen solutions" in accordance with the regulatory requirements. We could not find an official definition as to what constitutes a "medical screen solution", therefore our question is:

What is the definition of a "medical screening solution" as it applies to the regulatory requirements of 49 CFR 173.50 (g)?

Best Regards,

A handwritten signature in black ink that reads "Nicholas Pagerly".

Nicholas Pagerly, Quest Diagnostics Subject Matter Expert
Hazmat Transportation and Regulatory Compliance

- In your opinion, is this draft definition (highlighted in red) correct or does it need to be revised/rewritten?

Any comments/edits you or your staff can provide to improve its accuracy would be greatly appreciated.

Draft Letter Language:

Although PHMSA does not define the term **medical screening solutions** in the HMR, it is the opinion of this Office that in general this term means any solution used to perform part or all of a screening test designed to identify an unrecognized disease in an individual or population that does not display any signs or symptoms of a disease. As this term is used in § 173.150(g), medical screening solutions means one or more solutions or concentrates sold as a retail product that contains 70 percent or less "UN 1170, Ethyl alcohol, 3 (flammable liquid), PG II or III," by volume for liquids or by weight for solids, that are placed in packagings with a liquid or solid material in conformance with the requirements prescribed in § 173.150(g).

Current § 173.150(g) HMR Regulatory Text Language:

§ 173.150 Exceptions for Class 3 (flammable and combustible liquids).

* * * * *

(g) Limited quantities of retail products containing ethyl alcohol. (1) Beverages, food, cosmetics and medicines, medical screening solutions, and concentrates sold as retail products containing ethyl alcohol classed as a flammable liquid or flammable solid containing not more than 70% ethyl alcohol by volume for liquids, by weight for solids are excepted from the HMR provided that:

(i) For non-glass inner packagings:

(A) The volume does not exceed 16 fluid ounces in capacity for liquids; or

(B) For volumes greater than 16 fluid ounces but not exceeding 1 gallon the company name and the words "Contains Ethyl Alcohol" are marked on the package;

(C) Solids containing ethyl alcohol may be packaged in non-glass inner packagings not exceeding 1 pounds capacity;

(D) For weight greater than one pound up to 8 pounds the company name and the words "Contains Ethyl Alcohol" are marked on the package.

(ii) For glass inner packagings:

(A) The volume does not exceed 8 fluid ounces in capacity; or

(B) For volumes greater than 8 fluid ounces to 16 fluid ounces the company name and the words "Contains Ethyl Alcohol" are marked on the package;

(C) Solids containing ethyl alcohol may be packaged in glass inner packagings not exceeding ½ pound;

(D) For weight greater than ½ pound up to 1 pound the company name and the words "Contains Ethyl Alcohol" are marked on the package.

(iii) The net liquid contents of all inner packagings in any single outer packaging may not exceed 192 fluid ounces. The net solid contents of all inner packagings in any single outer packaging may not exceed 32 pounds. The gross weight of any single outer package shipped may not exceed 65 pounds; Inner packagings must be secured and cushioned within the outer package to prevent breakage, leakage, and movement.

Andrews, Steven (PHMSA)

From: Meechan, Paul J. (CDC/OCOO/OSSAM) <iww9@cdc.gov>
Sent: Tuesday, September 30, 2014 5:28 PM
To: Andrews, Steven (PHMSA)
Subject: RE: RE: Definition of "Medical Screening Solutions"

Hello Steve- Sorry, it took a few days to get a response from my medical team here. Since this is looking at the retail side, the probability of other hazardous materials is low and therefore we agreed the language is good. We spent a good bit of time discussing whether the screening solutions would only be retail, but since this is a definition, it is not looking at those only used within a medical facility and would include those used by home testers. After we resolved that, the language appeared to us to be good.

Thanks for your patience.
Paul

From: steven.andrews@dot.gov [mailto:steven.andrews@dot.gov]
Sent: Tuesday, September 23, 2014 9:37 AM
To: Meechan, Paul J. (CDC/OCOO/OSSAM); Meechan, Paul J. (CDC/OCOO/OSSAM)
Subject: FW: RE: Definition of "Medical Screening Solutions"

From: Edmonson, Eileen (PHMSA)
Sent: Monday, September 22, 2014 1:16 PM
To: Andrews, Steven (PHMSA)
Cc: Foster, Glenn (PHMSA)
Subject: FW: RE: Definition of "Medical Screening Solutions"

Steven - If you wish to call Dr. Meechan or a member of his staff to make sure they have no comment, I've included his contact information below:

From: Edmonson, Eileen (PHMSA)
Sent: Thursday, July 24, 2014 2:59 PM
To: MPH Paul Meechan PhD (iww9@cdc.gov)
Cc: Foster, Glenn (PHMSA)
Subject: RE: Definition of "Medical Screening Solutions"

Hello Dr. Meechan,

Mr. Nicholas Pagerly has asked my agency to define the wording "medical screening solutions" as we use this term in 49 CFR 173.150(g) of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) for limited quantities of ethyl alcohol. I've repeated the regulatory language that contains this wording below for your convenience. The HMR sometimes contains words it does not define. The Pipeline and Hazardous Materials Safety Administration (PHMSA) has taken the position in past clarification letters that in many cases it will accept definitions for these words as they appear in a standard or technical dictionary. However, we have not found to date a dictionary definition for the wording "medical screening solutions." We have attempted to create this definition in our draft response to Mr. Pagerly. I have repeated the pertinent language below. As the lead federal agency for the detection, prevention, and control of diseases and other preventable conditions, we thought it best to consult the Centers for Disease Control and Prevention on the accuracy of this draft definition.

(2) Beverages, food, cosmetics and medicines, medical screening solutions, and concentrates sold as retail products containing ethyl alcohol classed as a flammable liquid or flammable solid containing more than 70% ethyl alcohol by volume, by weight for solids are excepted from the HMR provided that:

(i) For inner packagings containing liquids the volume does not exceed 8 fluid ounces in capacity;

(ii) Solids containing ethyl alcohol are not packed in inner packagings exceeding 1/2 pound in weight;

(iii) The net liquid contents of all inner packagings in any single outer packaging may not exceed 192 fluid ounces. The net solid contents of all inner packagings in any single outer packaging may not exceed 32 pounds. The gross weight of any single outer package shipped may not exceed 65 pounds. Inner packagings must be secured and cushioned within the outer package to prevent breakage, leakage, and movement.

(3) For transportation by passenger or cargo aircraft, no outer package may be transported which contains an inner packaging exceeding:

(i) 16 fluid ounces of flammable liquid, or

(ii) 1 pound of solids containing flammable liquid.

Thank you in advance for your assistance.

Sincerely,

Eileen Edmonson
Transportation Regulations Specialist
Pipeline and Hazardous Material Safety Administration
U.S. Department of Transportation
1200 New Jersey Avenue, SE, PHH-12
Washington, DC 20590
202-366-4481 (w)
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eileen.edmonson@dot.gov (e-mail)
infocntr@dot.gov (Hazmat Info Center e-mail)

Edmonson, Eileen (PHMSA)

From: LaValle, Diane (PHMSA)
Sent: Thursday, May 29, 2014 1:20 PM
To: Edmonson, Eileen (PHMSA); Herzog, Kenneth (PHMSA)
Subject: RE: Question re: DOT-SP 9275 Background Documents

The special permit only covered ethyl alcohol solutions. It never covered anything more than that. I googled medical screening solution, it seems that term pertains to anything used for testing purposes, from drug testing to testing for diseases. We don't use the terms in any other permits. Let me know if you need something more.
Diane

From: Edmonson, Eileen (PHMSA)
Sent: Thursday, May 29, 2014 1:11 PM
To: LaValle, Diane (PHMSA); Herzog, Kenneth (PHMSA)
Subject: Question re: DOT-SP 9275 Background Documents

Diane and Kenny,

I'm looking for background information on DOT-SP 9275 that discusses/explains/defines the term "medical screening solutions." I have to revise a letter that is asking us to define that term. I'm aware that there are several types of screening solutions used in laboratory work.

- Did this special permit only authorize those containing limited quantities of ethyl alcohol or was it broader than that?
- Do we have other or have we had other DOT-SP's that also discuss screening solutions, medical or otherwise?

I've included the language in the HM-233C preamble that discusses this DOT-SP. I will appreciate any information you can provide on this.

DEPARTMENT OF TRANSPORTATION
Pipeline and Hazardous Materials
Safety Administration
49 CFR Parts 107, 171, 172, 173, 175
and 178
[Docket No. PHMSA-2011-0158 (HM-233C)]
RIN 2137-AE82
Hazardous Materials: Adoption of
Certain Special Permits and
Competent Authorities Into
Regulations
AGENCY: Pipeline and Hazardous
Materials Safety Administration
(PHMSA), DOT.
ACTION: Final rule.

*A. Consumer Products Containing
Liquids and Solids Containing Ethyl
Alcohol*

DOT-SP 9275 authorizes the

transportation in commerce of certain beverages, foods, cosmetics, medicines, **medical screening solutions** and concentrates containing ethyl alcohol and exempts these shipments from the provisions of HMR. This special permit has been in effect since at least 1985 and had been utilized by hundreds of companies. However, on August 18, 2011 PHMSA found that SP 9275 did not provide a level of safety at least equivalent to the HMR due to the lack of hazard communications markings. This was discovered during PHMSA's review of all special permits as required by the DOT Office of the Inspector General (OIG) to ensure all special permits met an equivalent level of safety. PHMSA issued a revised version of SP 9275 to address the lack of hazard communication markings on August 18, 2011.

In response to the NPRM, PHMSA received several comments on how to adopt this special permit. Several commenters opposed the requirement for the shipments under the proposed section to require the words "contains ethyl alcohol" on the outside of the package. After careful consideration of these comments, PHMSA is adopting the special permit without requiring the words "contains ethyl alcohol" for shipments of ethyl alcohol in quantities not exceeding 8 fluid ounces in glass containers and not exceeding 16 fluid ounces in non-glass containers. For shipments of ethyl alcohol (not more than 70% concentration) in quantities greater than 8 fluid ounces in glass containers and greater than 16 ounces in non-glass containers, the words "contains ethyl alcohol" are required on the outside of the package. Shipments of ethyl alcohol in quantities of 8 ounces or less are not required to be marked with the words 'contains ethyl alcohol.'" (This would apply to both greater than and less than 70% concentration.)

Therefore, PHMSA is adopting the terms of SP 9275 as revised on August 18, 2011 with modification. PHMSA is adopting this special permit to allow certain limited quantities of ethyl alcohol to be excepted from the applicable provisions of the HMR that require the packages to be marked with the words "Contains Ethyl Alcohol." PHMSA is adding § 173.150(g) to allow for the shipment of limited quantities of ethyl alcohol of not exceeding 8 fluid ounces in glass containers and not exceeding 16 fluid ounces for non-glass containers without the term "contains ethyl alcohol" marked on the outside of the package. Packages containing 8 fluid ounces to 1 gallon shipped under this

section require the marking “contains ethyl alcohol” on the outside of the package.

Thanks,

Eileen Edmonson
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