



U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

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

FEB 17 2016

Mr. Ted McLaughlin
Chief Executive Officer
DiSorb Systems, Inc.
1800 West Indiana Avenue
Philadelphia, PA 19132

Reference No.: 15-0152

Dear Mr. McLaughlin:

This letter is in response to you and your staff's e-mails and telephone calls, your July 23, 2015 letter, and the October 14, 2015 meeting that you, Steve Savad (President, DiSorb Systems, Inc.), and Ed Krisiunas (MT(ASCP) MPH, President, WNNW International, LLC) attended with several Pipeline and Hazardous Materials Safety Administration (PHMSA) staff members at the Department of Transportation headquarters in Washington, DC. Specifically, you requested clarification on how the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) apply to the absorbent gel your company manufactures for use in suction canisters and with other liquid wastes described as "UN 3291, Regulated medical waste, n.o.s., 6.2 (infectious substance), Packing Group (PG) II" (RMW). We have paraphrased your questions and answered them below.

- Q1. Do the HMR permit suction canisters containing RMW to be transported with their contents in a liquid state?
- A1. The answer is yes, provided the completed package meets the HMR requirements for transporting liquid RMW (e.g., see §§ 172.24, 173.24a, 173.24b, 173.197 (a), (b) and (e)(2)).
- Q2. If suction canisters that contain the liquid contents we described earlier are placed in a larger container, can that larger container be placed in transportation without a sufficient amount of absorbent material inside the outer packaging to solidify the liquid contents of the suction canisters if they leak or break?
- A2. The HMR specifically require packages that contain inner packagings of Division 6.2 liquids include sufficient amounts of absorbent and cushioning material between the inner and outer packagings to absorb, not solidify, the entire liquid contents (see §§ 173.27(e)(1), 173.196(a)(4), 173.197(c)(2) and (e)(1), 173.199(b)(2)). Further, the HMR require that absorbent material in a hazardous materials packaging must not be capable of either reacting dangerously with the contents of the inner packaging or

having its protective properties significantly weakened in the event of leakage (see §§ 173.24(b)(2) and (d)(e), and 173.24a(a)(3)). However, please note the HMR do not specifically prohibit absorbent material from solidifying liquid Division 6.2 contents, provided the solidified contents do not adversely affect the safe transport of the material (e.g., by compromising the performance of the packaging).

- Q3. I understand that under § 173.197(e)(2) liquids, such as blood, are authorized in RMW packagings that cannot exceed 5 gallons per inner packaging. Therefore, if a one-gallon size liquid suction canister that contains product in a liquid state is placed directly into a red bag in a non-bulk package, do the contents of the suction canister need to be converted into a solid state, or does it need to be packaged with absorbent material? Should the canister be placed in a red bag by itself with absorbent material?
- A3. Your understanding is correct that under § 173.197(e)(2) RMW liquids, such as blood that meets the definition of a Division 6.2 material, are authorized in inner packagings that cannot exceed 19 L (5 gallons). However, the HMR do not require the liquid contents of a suction canister to be converted into a solid physical state. Section 173.197(e)(2) requires that inner packagings placed in Large Packagings, wheeled carts, and bulk outer packagings are rigid and conform to applicable provisions in 49 CFR Part 173, Subpart B. The 19-L inner packaging limit does not exist under § 173.197(b) which permits non-bulk, United Nations standard packagings to contain up to 450 L (119 gallons) of liquid per inner packaging. Further, under § 173.134(c), RMW may be placed in packagings that comply with 29 CFR 1910.1030 bloodborne pathogen packagings, which permit use of a red bag as an inner packaging in a combination packaging, provided the packaging also complies with §§ 173.24 and 173.24a, is transported by private or contract carrier, or is transported by a private or contract carrier used exclusively to transport certain RMW.
- Q4. Can a large amount of liquid in its own inner packaging (e.g., a suction canister) be transported in a non-bulk package of RMW under § 173.24a(c)(2)? Does § 173.24a(c)(2) limit the quantity of liquid per package to one ounce?
- A4. Section 173.24a(c)(2) permits a non-bulk packaging that contains inner non-bulk packagings of Division 6.2 materials to contain only three types of additional hazardous materials: 1) refrigerants authorized under the HMR; 2) anticoagulants used to stabilize blood or plasma; or 3) small quantities of Class 3 (flammable liquid), Class 8 (corrosive), Class 9 (miscellaneous), or other materials in PG II or III that are used to stabilize or prevent the degradation of the Division 6.2 sample. This section also limits these stabilizer/preservative materials to 30 mL (1 ounce) or 30 g (1 ounce) or less per each inner packaging, and the total amount of stabilizer/preservative to 4 L (1 gallon) or 4 kg (8.89 pounds) per completed package.
- Q5. If liquid blood is acceptable in a bulk package, does the absence of the subject “liquids in a non-bulk package” suggest that liquids are not authorized in a non-bulk package?

A5. The answer is no, the HMR require that a package authorized to contain liquid hazardous materials must comply with the applicable provisions for the quantity and type of that material.

Q6. What does “absorbent material” mean under the HMR?

A6. The HMR do not define “absorbent material.” However, as this term is used in §§ 171.8 (outer packaging), 173.6(a)(4), 173.196(a)(4), 173.197(c)(2) and (e)(1), 173.199(b)(2) and (d)(1), and 178.609(d)(4) and (i)(3)(v), it is the opinion of this Office that “absorbent material” means a material that physically soaks up or takes in and retains liquid during transportation.

Q7. Does DiSorb’s absorbent gel meet the HMR’s definition of an absorbent material? If not, what actions must DiSorb take for PHMSA to authorize it as an absorbent material under the HMR?

A7. The answer is yes, provided it performs as described in Answer A6.

I hope this information is helpful. Please contact us if we can be of further assistance.

Sincerely,

A handwritten signature in cursive script that reads "T. Glenn Foster". The signature is written in black ink and is positioned above the typed name.

T. Glenn Foster
Chief, Regulatory Review and Reinvention Branch
Standards and Rulemaking Division

Edmonson
173.134
Definitions and Exception
15-0152

Goodall, Shante CTR (PHMSA)

From: Edmonson, Eileen (PHMSA)
Sent: Thursday, July 23, 2015 2:50 PM
To: Dodd, Alice (PHMSA); Goodall, Shante CTR (PHMSA)
Subject: FW: DoT questions

Ladies,

Can one of you please log this letter in to filemaker and assign it to me?

Thanks!

Eileen Edmonson
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From: Ted McLaughlin [<mailto:tedm@disorb.com>]
Sent: Thursday, July 23, 2015 11:08 AM
To: Edmonson, Eileen (PHMSA); Foster, Glenn (PHMSA); Betts, Charles (PHMSA)
Cc: Stevens, William (PHMSA); Steve Savad
Subject: DoT questions

Eileen, Glenn & Charles:

Eileen - let me thank you again for your support in helping us clearly understand the DoT's regulations governing the transportation of RMW, specifically, if it is ever acceptable for a hospital to ship suction canisters when the contents of the canisters (blood, saline solution, etc) are in a liquid state. Please understand, as a manufacturer of solidifiers used to solidify and disinfect suction canisters, we are in frequent contact with the RMW generators i.e. hospitals. We are often asked by hospitals about the DoT regulations surrounding the transport of the RMW, specifically the regulations pertaining to transporting hospital suction canisters which are filled w blood, saline solution, etc. At the moment, there is ambiguity as to when suction canisters must be solidified prior to being transported and if there is an exception to the solidification requirement. As key figures in this space, it is important that we can accurately communicate your department's regulations to the RMW generators so they may be compliant.

I want to be clear in my ask of you. In short, Is there ever a case where suction canisters containing Regulated Medical Waste may be transported with their contents in a liquid state? If these same suction canisters are placed into a larger container, with their contents in liquid form, is there ever a case when that larger container can be transported without a sufficient amount of absorbent material in the outer package to solidify the suction canister contents in the event the canister leaks or breaks?

While we have carefully read all of the previous correspondence and your department's answers to related inquiries, we feel it necessary to have our specific questions answered so we can accurately respond to RMW generators we deal with. We respect their desire to be compliant in their RMW transport

requirements. Further to the aforementioned, perhaps you can offer further interpretation concerning 173.134 & 173.197 I understand, according to 173.197(e)(2) liquids (blood) are authorized in large packages of RMW not to exceed 5 gallons per package. So, can a 1 gallon-sized liquid suction canister be placed directly into a red bag in a liquid state in a non-bulk (less than 119 gallon capacity) package? Or, does this suction canister need to be converted into a solid state, or be packaged w absorbent material? Or should the canister be placed in a red bag by itself with absorbent material? Can a large amount of liquids in its own inner package (suction canister) be transported in a non bulk package of RMW Under 173.24a(c)2? According to this regulation, is the liquid state limited to 1 ounce?

If liquid blood is acceptable in a bulk package, does the absence of the subject "liquids" in a non-bulk package suggest that liquids are not authorized in a non-bulk package?

Thank you in advance for your assistance.



Ted McLaughlin
CEO
DiSorb Systems, Inc.
1800 West Indiana Ave
Philadelphia, PA
215-207-9010 x201



Hello Ted,

FYI - I also found this letter on RMW suction canisters.

3/21/2003 RefNo 02-0270

<http://docketsinfo.dot.gov/reports/rspa/2003-03//020270.pdf>.

Eileen Edmonson
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From: Edmonson, Eileen (PHMSA)
Sent: Tuesday, July 21, 2015 12:23 PM
To: 'Ted McLaughlin'
Cc: Steve Savad; Stevens, William (PHMSA); Foster, Glenn (PHMSA)
Subject: RE: DoT regulation § 173.197 Regulated medical waste

Hello Ted,

I apologize for the delay in responding. I've been working on several rush projects lately and today is no exception.

I found website links to two letters we issued that discussed solidifiers and regulated medical waste (RMW), but you've probably already seen them.

5/15/2000 Ref No 99-0311

<http://docketsinfo.dot.gov/reports/rspa/2000-05/990311.pdf>

1/26/12 Ref No 11-0261

<http://www.phmsa.dot.gov/staticfiles/PHMSA/Interpretations/2011/110261.pdf>

The HMR does not require the use of solidifiers for RMW, so I can't issue a letter that says it does. It sounds like what you want to do is petition us to include solidifiers as a requirement for packaging RMW in the HMR. If that is correct, we'd be happy to meet with you to discuss if this might be possible. Please let me know if this is what you are asking. If the answer is yes, I'll present your request to my supervisors for their okay and set the meeting up with the interested parties.

Sincerely,

Eileen Edmonson

USDOT/PHMSA

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