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

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

MAY 15 2000

Mr. James L. Dunn
Vice President Product Development
Dornoch Medical Systems, Inc.
4032 Riverside Street
Riverside, MO 64150

Ref. No. 99-0311

Dear Mr. Dunn:

This is in response to your November 18, 1999 and March 6, 2000 letters requesting clarification on requirements for shipping regulated medical waste (RMW) under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180), and the use of a product you referred to as a "solidifier."

You state the purpose of this solidifying product is to take a liquid-filled suction canister that may have large blood clots and gel the solution into a less liquid state. The end result is more like a gelatin than a free flowing liquid. The blood and body fluids would be considered potentially infectious, requiring the container to be disposed of as infectious waste. You also state that these solidifiers do not always stay in the gelled state, and that warm temperatures often re-liquify the material.

It is your understanding that RMW with free flowing liquids may not be placed in roll-off or bulk packaging. Your understanding is correct. Bulk packagings are not authorized for the transportation of RMW except under the terms of an exemption. Section 173.134(c)(2) requires that a RMW be packaged as prescribed in § 173.197 in non-bulk specification packagings meeting the Packing Group II performance level. In addition, you state that you have several questions regarding the shipment of these waste products. Your questions are paraphrased and answered as follows:

Q1. Have hospitals or the manufacturers of the solidifier product requested or received an exemption for the use of this product to allow the liquids to be placed into roll-off or bulk packaging containers for transportation of the RMW. If so, could I get a copy of the exemption?

A1. We have not received any applications for exemptions from hospitals or manufacturers of the solidifiers to use solidifiers for this purpose.

Q2. Does the Department of Transportation (DOT) ask for testing results or work off the honor system?

A2. If a manufacturer applies for an exemption, we will require the submission of laboratory data and test results as part of the exemption application review process.

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Q3. Does the DOT consider blood clots a liquid that would have to be handled accordingly?

A3. A material meets the defining criteria for a liquid in § 171.8 of the HMR if its initial melting point is 20°C (68° F) or lower at 101.3 kpa (14.7 psi). In addition, a viscous material for which a specific melting point cannot be determined must be subjected to the procedures specified in ASTM D 4359, "Standard Test Method for Determining Whether a Material is Liquid or Solid."

Q4. Does the DOT consider a gelled liquid that can return to a liquid state a liquid or a solid?

A4. If a hazardous material meets the definition of a solid under § 171.8 when packaged and offered for transportation, it is a solid material under the HMR. However, the tests referred to in § 171.8 for determining whether a material is a liquid are performed at ambient temperatures. If a solid hazardous material will likely encounter temperatures in transportation that may cause the material to become a liquid, § 173.24(e)(5) requires that the packaging be capable of containing the hazardous material in the liquid state. In addition, § 173.134(c)(2) requires that RMW be packaged as prescribed in § 173.197 in a non-bulk specification packaging meeting the Packing Group II performance level. Section 173.197 also requires that the packagings be rigid, leak resistant, impervious to moisture, of sufficient strength to prevent tearing or bursting under normal conditions of use and handling, sealed to prevent leakage during transport, puncture resistant for sharps, and break resistant and tightly lidded or stoppered for fluids in quantities greater than 20 cubic centimeters.

Q5. What does the DOT recommend for the management of liquid RMW in the hospital setting?

A5. DOT does not regulate the management of RMW in a hospital setting. We regulate the transportation of RMW in commerce.

Q6. Is the use of the product solidifier a way to get around the DOT regulations for free flowing liquids?

A6. See response in A4.

Q7. Since the U.S. Environmental Protection Agency (EPA) has determined that the solidifying product known as "Premicide" does not treat blood clots in suction canisters and should not be used in this manner, should the transportation of these suction canisters with blood clots fall under the DOT's jurisdiction and not be transported as treated waste?

A7. Yes. A blood clot treated with chemical disinfectant, such as that contained in Premicide, that still meets the hazard of an infectious substance does not qualify for exception from the HMR as treated material. See § 173.134(b)(iv).

Q8. What would be the associated fines for the transportation of untreated blood and body fluids from the DOT?

A8. The associated fines will depend on the violation. Appendix A to Subpart D of Part 107, "Guidelines for Civil Penalties and List of Frequently Cited Violations," provide general guidance for making initial decisions for civil penalties in enforcement cases.

I hope this answers your inquiry.

Sincerely,

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

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Associate Administrator for Hazardous Materials Safety,
Research and Special Programs Administration
U.S. Department of Transportation
400 7th Street SW
Washington DC
20590-0001
Route DHM-10

ATTENTION: Department of Interpretation
Ref: Liquid Infectious Waste Exemption #E 10821
DOT Exemption for Bulk Packaging and restriction of free flowing liquids
By Phil Olsen

Dear Mr. / Ms. ,

I spoke to Jeff Fetner, Regulatory Specialist and Ann Mazzullo, and Phil Olsen from the DOT about a specific product used on the market today in the hospital setting. They have referred me to you. The generic name for this product is "solidifier". The name itself is a misnomer. The purpose of this product is to take a liquid filled suction canister that may have large blood clots and gel the solution into a less liquid state. The end result is more like a gelatin vs. free flowing liquid. The blood and body fluids would be considered potentially infectious requiring the container to be placed in the infectious waste stream.

The understanding I have for the DOT regulation of infectious waste handling requires that free flowing liquids require special handling and can not be placed in roll off or bulk packaging. I have several questions in regards to the use of "solidifiers" and if the use of these types of products would justify the liquid containers to be placed into non specialized infectious waste containers. Solidifiers do not always stay in the gelled state. Warm temperatures will often re-liquefy the gel. The amount of solidifier used impacts the performance of the product. The use of this product is found in approximately 30% of the hospitals.(2000) The average hospital uses approximately 12,000 1/2 gallon canisters a year. This is a significant amount of fluid that is being transported from hospitals.

My questions:

1) Have hospitals or the manufacturers of the solidifier product requested or received an exemption for the use of this product to allow the liquids to be placed into roll off or bulk packaging containers for transportation of the infectious waste. If so, could I get a copy of the exemption?
2) Have the manufactures provided the DOT with the necessary laboratory data that proves that the gelled fluids would not return to a liquid state in warmer climates such as hospital storage areas or waste trucks? Does the DOT ask for testing results or work off the honor system?
3) Does the DOT consider blood clots a liquid that would have to be handled accordingly.
4) Does the DOT consider a gelled liquid that can return to a liquid state a liquid or a solid?
5) What does the DOT recommend for the management of liquid infectious waste in the hospital setting?
6) Is the use of the product "solidifier" a way to get around the DOT regulations of free liquids?

I appreciate your attention and response to these issues.

Thank You,

James L. Dunn RN
Vice President
Product Development

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