



U.S. Department  
of Transportation

**Pipeline and  
Hazardous Materials Safety  
Administration**

JUL -3 2006

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

Mr. E.A. Altemos  
HMT Associates, L.L.C.  
603 King Street  
Alexandria, VA 22314-3105

Ref. No. 06-0102

Dear Mr. Altemos:

This is in response to your April 13 2006 letter regarding the small quantity exception in the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Specifically you ask if you may continue to ship small quantities of ethylene oxide sterilization devices under the provisions of § 173.4(c).


According to your letter, Andersen Products holds CA-9803005, which authorizes the transportation of ethylene oxide sterilization devices under the provisions of § 173.4 and other conditions specified in the approval.

On March 22, 2006, PHMSA published a final rule [71 FR 14586; Docket HM-228] entitled "Hazardous Materials: Revision of Requirements by Aircraft". The final rule adopted a new special provision A59 authorizing the transportation by aircraft of ethylene oxide sterilization devices under the provisions of § 173.4 and the conditions and limitations specified in Special Provision A59. The final rule also adopted a new § 173.4(a)(11) limiting the hazardous materials eligible for transportation by aircraft under the small quantity exception to those materials authorized aboard passenger aircraft. In your letter you note ethylene oxide is prohibited for transportation by passenger aircraft.

Section 173.4(c) authorizes the Associate Administrator to approve Class 2 materials for transportation under the small quantity exceptions. Packages authorized under § 173.4(c) must conform to § 173.4(a)(1) through (a)(10). Since your material meets the requirements of § 173.4(a)(1) through (a)(10), CA 9803005 remains valid.

I hope this information is helpful. Please contact us if you require additional assistance.

Sincerely,

  
John A. Gale  
Chief, Standards Development  
Office of Hazardous Materials Standards



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§173.4  
Small Quantity Excepti  
06-0102  
E.A. ALTEMOS  
PATRICIA A. QUINN

WRITER'S DIRECT DIAL NUMBER

(703) 4549-0727, Ext. 11

April 13, 2006

Mr. Del Billings  
Director, Office of Hazardous Materials  
Special Permits and Approvals (PHH-30)  
Pipeline and Hazardous Materials  
Safety Administration  
Department of Transportation  
Washington, D.C. 20590-0001

Re: CA-9803005; request for interpretation

Dear Mr. Billings:

On behalf of Andersen Products of Haw River, North Carolina, this is to request confirmation of our understanding of the relationship between CA-9803005, issued to Andersen Products, and amendments to the Hazardous Materials Regulations (HMR) recently adopted under the Docket No. HM-228 final rule.

Andersen Products ("Andersen") is a distributor of ethylene oxide sterilization systems used in doctors' offices, dentists' offices, hospitals, clinics and other medical facilities for the sterilization of medical instruments. The ethylene oxide for these systems is supplied in glass ampoules, each with a volume of not more than 20 ml. Andersen is holder of CA-9803005 (First Revision) which authorizes the transport of these ampoules under the "small quantity exceptions" in section 173.4 of the HMR, and subject to any additional conditions and limitations in the approval. The approval was issued pursuant to the provisions of 173.4(c), which permits materials of certain hazard classes (including Class 2) not normally authorized for transport under the exceptions in 173.4, to be transported in accordance with those exceptions with the approval of the Associate Administrator. This paragraph specifically requires that packages containing any material transported under such an approval conform to the requirements of 173.4(a)(1) through (a)(10). As you know, ethylene oxide is classified in Division 2.3, Hazard Zone D (although toxicity tests more recently performed suggest that ethylene oxide may not actually meet the criteria for classification in Division 2.3).

**HMT ASSOCIATES, L.L.C.**

Mr. Del Billings  
April 13, 2006  
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Since issuance of the approval in 1998, millions of ampoules have been transported under the terms of the approval without any incident resulting in leakage of the contents.

The Docket No. HM-228 final rule, published on March 22, 2006, adopted a new Special Provision A59 authorizing the transportation by aircraft of ethylene oxide sterilization devices containing less than 30 ml per inner packaging under the provisions of 173.4, subject to certain conditions and limitations as stated in the new special provision. Importantly, the new special provision addresses only transport by aircraft, and would not authorize the ground transport of these devices under the exceptions in 173.4. Also adopted under the final rule, was a new paragraph 173.4(a)(11)(i) that requires, for transportation by aircraft, that any material transported under the exceptions in 173.4 be a material authorized to be carried aboard passenger-carrying aircraft.

It is our understanding that the newly adopted Special Provision A59 has no impact on the existing CA-9803005. That is, ethylene oxide may continue to be transported domestically under the conditions and limitations in that approval by all authorized modes of transport (including air transport), without regard to the new Special Provision A59. Moreover, with regard to the applicable provisions in 173.4, we note that, importantly, the provision pursuant to which CA-9803005 is issued specifically requires that packages of "approved" materials conform to all requirements in 173.4(a)(1) through (10), but does not require compliance with the new paragraph 173.4(a)(11)(i). Consequently, 173.4(c) continues to authorize the Associate Administrator to approve the transport of a Class 2 materials by all modes of transport (including by aircraft) under the exceptions in 173.4, notwithstanding that a particular material would not normally be permitted for transport by passenger-carrying aircraft.

Confirmation, at your earliest convenience, of our understanding that the new Special Provision A59 and the new paragraph 173.4(a)(11)(i) adopted under the Docket No. HM-228 final rule do not in any way impact the provisions, conditions and limitations in the existing CA-9803005 - including as these relate to domestic transport by aircraft - will be very much appreciated.

Thank you for your consideration of this matter.

Sincerely,



E. A. Altemos