

November 4, 2005



U.S. Department
of Transportation

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

**Pipeline and
Hazardous Materials
Safety Administration**

DOT-SP 12784
(SECOND REVISION)

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: (See individual authorization letter)
2. PURPOSE AND LIMITATION:
 - a. This special permit authorizes the transportation in commerce of certain non-DOT specification nonrefillable containers containing chlorodifluoromethane (R22), classed as ORM-D. This special permit provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein.
 - b. The safety analyses performed in development of this special permit only considered the hazards and risks associated with transportation in commerce. The safety analyses did not consider the hazards and risks associated with consumer use or other uses not associated with transportation in commerce.
3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR §§ 173.304a(a)(1), 173.306(a), and 175.3 in that non-DOT specification containers are not authorized packagings, except as specified herein.
5. BASIS: This special permit is based on the application of CryoSurgery, Incorporated dated October 3, 2005, submitted in accordance with § 107.109.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identification Number	Packing Group
Consumer Commodity	ORM-D	N/A	N/A

7. SAFETY CONTROL MEASURES:

a. PACKAGING - Packagings prescribed are non-DOT specification nonrefillable containers designed, manufactured, and marked in accordance with DOT-SP 9393. The maximum water capacity of each container is 12.6 fluid ounces (22.7 cubic inches).

b. OPERATIONAL CONTROLS -

- (1) The product is intended for medical use.
- (2) Filling density may not exceed 75 percent.
- (3) The pressure of the lading at 70°F may not exceed 240 psig; and at 130°F, may not exceed 300 psig.
- (4) Containers must be shipped in strong outside packagings in accordance with 173.301(a)(9).
- (5) Each outside package may not contain more than 12 containers.

c. MARKING -

- (1) In addition to the "DOT-SP 9393" marking, each container must be marked "DOT-SP 12784" as specified in § 172.301(c).
- (2) Outside packagings are not required to be marked "INSIDE CONTAINERS COMPLY WITH DOT-SP 12784".

8. SPECIAL PROVISIONS:

a. Packagings may be reclassified as ORM-D and shipped as "consumer commodity" in accordance with § 173.306(h).

b. A person who is not a holder of this special permit who receives a package covered by this special permit may reoffer it for transportation provided no modification or change is made to the package or its contents and it is reoffered for transportation in conformance with this special permit and the HMR.

c. A current copy of this special permit must be maintained at each facility where the package is offered or reoffered for transportation.

d. Packagings permanently marked 'DOT-E 12784', prior to November 1, 2006 may continue to be used under this special permit for the remaining service life of the packaging or until the special permit is no longer valid. Packagings marked on or after November 1, 2006 must be marked 'DOT-SP 12784'.

e. Shipping papers displaying 'DOT-E 12784' may continue to be used until November 1, 2006, provided the special permit remains valid.

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle, rail freight, cargo vessel, cargo aircraft only, and passenger-carrying aircraft.

10. MODAL REQUIREMENTS: A current copy of this special permit must be carried aboard each aircraft used to transport packages covered by this special permit. The shipper must furnish a current copy of this special permit to the air carrier before or at the time the shipment is tendered.

11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this special permit and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq:

o All terms and conditions prescribed in this special permit and the Hazardous Materials Regulations, 49 CFR Parts 171-180.

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- o Persons operating under the terms of this special permit must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
- o Registration required by § 107.601 et seq., when applicable.

Each "Hazmat employee", as defined in § 171.8, who performs a function subject to this special permit must receive training on the requirements and conditions of this special permit in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this special permit, including display of its number, when this special permit has expired or is otherwise no longer in effect.

Under Title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU)—"The Hazardous Materials Safety and Security Reauthorization Act of 2005" (Pub. L. 109-59), 119 Stat. 1144 (August 10, 2005), amended the Federal hazardous materials transportation law by changing the term "exemption" to "special permit" and authorizes a special permit to be granted up to two years for new special permits and up to four years for renewals.

12. REPORTING REQUIREMENTS: Shipments or operations conducted under this special permit are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 - Immediate notice of certain hazardous materials incidents, and 171.16 - Detailed hazardous materials incident reports. In addition, the grantee(s) of this special permit must notify the Associate Administrator for Hazardous Materials Safety, in writing, of any incident involving a package, shipment or operation conducted under terms of this special permit.

Issued in Washington, D.C.:



for Robert A. McGuire
Associate Administrator for
Hazardous Materials Safety

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration, Department of Transportation, Washington, D.C. 20590. Attention: PHH-31.

Copies of this special permit may be obtained by accessing the Hazardous Materials Safety Homepage at http://hazmat.dot.gov/sp_app/special_permits/spec_perm_index.htm Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

PO: CWFreeman/dl