



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

NOV 7 2003

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

DOT-E 12784
(FIRST REVISION)

EXPIRATION DATE: October 31, 2005

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: CryoSurgery, Incorporated
Nashville, Tennessee
2. PURPOSE AND LIMITATION:
 - a. This exemption authorizes the transportation in commerce of certain non-DOT specification nonrefillable containers containing chlorodifluoromethane (R22), classed as ORM-D. This exemption provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein.
 - b. The safety analyses performed in development of this exemption 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 exemption is based on the application of CryoSurgery, Incorporated dated October 30, 2003 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-E 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-E 9393" marking, each container must be marked "DOT-E 12784" as specified in § 172.301(c).
- (2) Outside packagings are not required to be marked "INSIDE CONTAINERS COMPLY WITH DOT-E 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 exemption who receives a package covered by this exemption 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 exemption and the HMR.

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

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 exemption must be carried aboard each aircraft used to transport packages covered by this exemption. The shipper must furnish a current copy of this exemption 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 exemption 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 exemption and the Hazardous Materials Regulations, 49 CFR Parts 171-180.

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 exemption must receive training on the requirements and conditions of this exemption in addition to the training required by §§ 172.700 through 172.704.

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may use or apply this exemption, including display of its number, when this exemption has expired or is otherwise no longer in effect.

12. REPORTING REQUIREMENTS: The carrier is required to report any incident involving loss of packaging contents or packaging failure to the Associate Administrator for Hazardous Materials Safety (AAHMS) as soon as practicable. (Sections 171.15 and 171.16 apply to any activity undertaken under the authority of this exemption.) In addition, the holder(s) of this exemption must inform the AAHMS, in writing, of any incident involving the package and shipments made under the terms of this exemption.

Issued in Washington, D.C.:

Robert A. McGuire
Robert A. McGuire
Associate Administrator for
Hazardous Materials Safety

NOV 7 2003
(DATE)

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

Copies of this exemption may be obtained by accessing the Hazardous Materials Safety Homepage at <http://hazmat.dot.gov/exemptions> Photo reproductions and legible reductions of this exemption are permitted. Any alteration of this exemption is prohibited.

PO: CWFreeman/sln