



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

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

MAR 24 2003

DOT-E 11799
(SIXTH REVISION)

EXPIRATION DATE: December 31, 2004

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: Cryonix, Inc.
Rockville, Maryland

(See Appendix A to this document for a list of additional grantees)

2. PURPOSE AND LIMITATION:

- a. This exemption authorizes the transportation in commerce of certain infectious substances in special packagings. 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.

3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 173.196(b) for testing and § 173.196(e)(2)(iii) in that direct cooling with liquid nitrogen must be used instead of exchangers.
5. BASIS: This exemption is based on the application of Cryonix Inc. dated February 26, 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
Infectious substances, affecting humans <i>Risk*</i>	6.2	UN2814	n/a
Infectious substances, affecting animals only*	6.2	UN2900	n/a

* Limited to Risk Group 1, 2 or 3 only, as defined in the U.N. Recommendations on the Transport of Dangerous Goods, Eleventh revised edition, 1999. Risk Group 4 materials are not authorized for transport by this exemption.

7. SAFETY CONTROL MEASURES:a. PACKAGING -

(1) Infectious substances, as listed in Paragraph 6, must be packed as follows: The substances, contained in sealed vials (primary receptacles), must be secured in individual cells of a box. The volume of culture material in each vial must not exceed 1.0 ml. Not more than eighty one (81) vials must be packed in a box. Not more than sixteen (16) filled and closed boxes must be packed in a plastic bag (secondary packaging) which must be heat sealed. Sufficient absorbent material must be placed between the primary and secondary packagings to absorb the entire contents of all primary receptacles in case of vial breakage or leakage. Not more than fifteen (15) plastic bags must be packed in a freezer with capacity not more than 0.7 cubic meters (25 cubic feet). The freezer serves as the outer packaging. Testing required in § 173.196(b) is waived.

(2) Voids in the storage space of the freezer must be filled with bubble wrap to prevent the contents from shifting.

(3) All freezer doors must be secured with safety latches and straps to prevent opening during transportation.

(4) The infectious substances in the freezers must be kept frozen at all times within the operating temperature range of -20°C to -75°C by using liquid nitrogen heat exchangers or dry ice. The amounts of liquid nitrogen or dry ice carried on the transport vehicle must be sufficient to keep the infectious substances within the operating temperature range for at least twice the estimated travel time.

(5) All freezers must be secured against movement in the transport vehicle.

(6) The freezers are constructed of double-walled steel with insulation material between the walls.

b. OPERATIONAL CONTROLS -

(1) This exemption authorizes the transport of packages containing infectious substances using a specialized dedicated transport vehicle. The freezer on the dedicated transport vehicle must be precooled using liquid nitrogen coils, brought as closely as possible to the secondary packages, and wheeled back to the vehicle. Packages must be prepared, transported, and unpacked by the contract carrier.

(2) Not more than one transport vehicle may be operated at all times.

(3) Not more than eight freezers may be in a transport vehicle.

(4) Emergency refrigeration and spill response procedures must be in place and operational to address loss of refrigeration, delay in transportation or release of an infectious substance.

8. SPECIAL PROVISIONS:

None.

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle.

10. MODAL REQUIREMENTS: A current copy of this exemption must be carried aboard each motor vehicle used to transport packages covered by this exemption.

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 E. McGuire
Associate Administrator for
Hazardous Materials Safety

MAR 24 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.

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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: Steve Hwang/KFW/sln

MAR 24 2003

The following are hereby granted party status to this exemption based on their application(s) submitted in accordance with § 107.107 or § 107.109, as appropriate:

Company Name City/State	Application Date	Issue Date	Expiration Date
Medical Equipment & Maintenance Company Rockville, MD	Feb 13, 2003	Mar 3, 2003	Dec 31, 2004
Pacific Bio-Material Management, Inc. Fresno, CA	Jan 6, 2003	Jan 30, 2003	Dec 31, 2004



RM Robert A. McGuire
Associate Administrator for
Hazardous Materials Safety