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

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

NOV 26 2002

DOT-E 12819
(FIRST REVISION)

EXPIRATION DATE: October 31, 2004

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: BBI - Biotech Research Laboratories, Inc.
Gaithersburg, MD

2. PURPOSE AND LIMITATION:

a. This exemption authorizes the transportation in commerce of certain infectious substances in special packagings transported by BBI-Biotech Research Laboratories, Inc. or a contract carrier. 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 in that an alternative packaging is authorized; and § 178.609 in that testing requirements for outer packagings are waived.

5. BASIS: This exemption is based on the application of BBI-Biotech Research Laboratories, Inc. (BBI-Biotech), dated November 26, 2002 submitted in accordance with 49 CFR § 107.109.

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6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Proper Shipping Name/ Hazardous Materials Description	Hazard Class/ Division	Identi-fication Number	Packing Group
Infectious substances, affecting humans, *(Risk Group 1 and 2 materials as defined in the U.N. Recommendations on the Transport of Dangerous Goods, Twelfth revised edition)* *	6.2	UN2814	N/A

*Risk Group (RG) 3 and 4 materials are not authorized under this exemption.

7. SAFETY CONTROL MEASURES:

a. PACKAGING - Infectious substances, as listed in paragraph 6 above, must be packed in freezers as follows:

(1) Primary receptacles must be watertight, sealed cryovials, containing culture material, not exceeding 1.0 ml in each vial. Primary receptacles must be tightly secured and packed with multi-layered polypropylene sheets within the freezer to prevent the contents from shifting. Freezers must be filled with sufficient absorbent material to absorb the entire contents of all primary receptacles.

(2) A water-resistant freezer, constructed of double-walled steel with insulation material between the walls, of adequate strength for its capacity, mass and intended use serves as the outer packaging. The testing required in § 173.196(b) is waived.

(3) Nitrogen freezers must be filled with approximately 4"-6" of liquid nitrogen prior to movement. Mechanical freezers of -70°C must be filled with sufficient dry ice prior to movement to keep the primary receptacles frozen at all times. Mechanical freezers of -20°C and +4°C must be filled with sufficient cold packs to keep the primary receptacles

at the proper temperature at all times. The amounts of liquid nitrogen, dry ice, or cold pack carried on the transport vehicle must be sufficient to keep the infectious substances within the operating temperature for at least twice the estimated travel time.

(4) All freezer doors must be securely closed with straps. All freezers must be secured against movement in the transport vehicles.

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 appropriate cooling medium, brought as closely as possible to the secondary packages before loading. Packages must be prepared by BBI-Biotech employees, transported by BBI-Biotech or a contract carrier under BBI- Biotech supervision, and unpacked by BBI-Biotech employees, as outlined in the application for exemption on file with the Office of Hazardous Materials Exemptions and Approvals.

(2) This exemption authorizes the transport of packages containing infectious substances to BBI-Biotech's facilities in Gaithersburg and Frederick, Maryland.

(3) Emergency refrigeration procedures must be in place and operational in the event of loss of refrigeration.

(4) No more than four freezers and no freezer containing RG 3 or 4 materials may be in a transport vehicle.

(5) No more than one transport vehicle may be operated at any time.

(6) An itemized list of contents and a label must be securely attached to the outside of each freezer.

(7) Emergency responders and back-up equipment necessary to mitigate a spill must accompany each transport vehicle.

(8) 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:

a. Emergency responders and escorts must carry a copy of packing lists for each freezer.

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

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:

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

- 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 the 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.:

NOV 2 6 2002

Robert A. McGuire
Associate Administrator
for Hazardous Materials Safety

(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: SHwang/sln