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

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

MAY 13 2002

DOT-E 12919
(SECOND REVISION)

EXPIRATION DATE: August 31, 2002

1. GRANTEE: Acambis, Inc.
Cambridge, MA

2. PURPOSE AND LIMITATION:

a. This emergency exemption authorizes the transportation in commerce of an infectious substance in a packaging system that has not been tested in accordance with the requirements for packagings and components specified in the Hazardous Materials Regulations (HMR). This exemption provides no relief from the 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) and 178.609 in that packagings which have not been tested in accordance with the HMR are not authorized except as specified herein.

5. BASIS: This emergency exemption is based on the application of Acambis, Inc. dated February 1, 2002, and as revised (Revision 1) on February 7, 2002, submitted in accordance with § 107.117 and a determination that it is necessary for immediate national security and additional information dated May 13, 2002.

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 (vaccinia virus)	6.2	UN2814	N/A

7. SAFETY CONTROL MEASURES:

a. PACKAGING - Packaging prescribed is a system composed of the following components:

(1) Inner packagings comprising:

(i) A watertight primary receptacle which is a stainless steel tank. The tank has a nominal capacity of 22 liters and is described in the Rutten Engineering Sterile Storage System standard specification for tank on file with the Office of Hazardous Materials exemptions and Approvals (OHMEA). The primary receptacle may not contain more than 16 liters of the concentrated vaccinia virus suspension.

(ii) The primary receptacle must be (heat) sealed in a watertight 6 mil polyethylene bag.

(iii) The primary receptacle must be placed into a watertight six mil polyethylene bag secondary packaging. The secondary packaging must be fitted with absorbent material (pads) that is sufficient to absorb the entire contents of the primary receptacle and with a high density polyethylene spacer to secure the primary receptacle. The secondary packaging must be sealed with duct tape (or equivalent). The assembled inner packagings must fit snugly in the outer packaging.

(2) Outer packaging: A 208 L (55 gallon) carbon steel drum manufactured and qualified to UN 1A2/X430/S and 1A2/Y1.6/200 requirements, as described in the Skolnik Industries, Inc. UN Drum Qualification Test Report on file with OHMEA.

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b. OPERATIONAL CONTROLS -

(1) Transportation is only authorized between Canton, Massachusetts and Baltimore, Maryland.

(2) Packages authorized under this exemption must be transported in a motor vehicle, under exclusive use, by a contract carrier.

(3) No carbon dioxide, solid (dry ice) may be present in the package.

8. SPECIAL PROVISIONS: A current copy of this exemption must be maintained at the 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 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.:

MAY 13 2002

(DATE)

Robert A. McGuire
Associate Administrator
for Hazardous Materials Safety

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration, U.S. Department of Transportation, 400 Seventh Street, SW, 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: GECushmac/DL