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

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

AUG 29 2002

DOT-E 13014
(SECOND REVISION)

EXPIRATION DATE: December 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 (dry vaccinia virus) 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 May 20, 2002, and additional information dated May 23, 2002, June 12, 2002, and August 20, 2002 submitted in accordance with § 107.117 and a determination that it is necessary for immediate national security purposes.

6. HAZARDOUS MATERIALS (49 CFR § 172.101): AUG 29 2002

| Hazardous Materials Description | | | |
|---|---|---|---|
| **Proper shipping name** | **Hazard Class/ Division** | **Identi-fication Number** | **Packing Group** |
| Infectious substances, affecting humans (dry vaccinia virus) | 6.2 | UN2814 | N/A |

7. SAFETY CONTROL MEASURES:

a. PACKAGING - Packaging prescribed is a system composed of an inner packaging and an outer packaging as described in the Acambis, Inc. applications dated May 20 and May 23, 2002 on file with the Office of Hazardous Materials Exemptions and Approvals.

(1) Inner packagings comprising:

(i) A watertight primary receptacle which is a glass vial with a capacity of approximately 5 ml. The vials may not be filled with more than 0.1 mg (approximately) of solid, dry vaccinia virus.

(ii) Filled and sealed vials must be packed in a fiberboard tray fitted with fiberboard dividers which provide a separate cell for each vial (i.e., one vial per cell).

(iii) Trays must be packed in a secondary packaging which is a non-DOT specification fiberboard box. The fiberboard box must be sealed with packing tape.

(iv) Fiberboard boxes must be wrapped with plastic stretch wrap. The wrap must cover and seal the entire outer surface of the wrapped fiberboard boxes. The assembled and wrapped inner packages must fit snugly in the outer packaging.

(2) Outer packaging: A molded plastic, hinged, single-lid case. Each case must be palletized. Each pallet must contain not more than two cases. Cases must be strapped securely to the pallet.

b. OPERATIONAL CONTROLS -

(1) Transportation is authorized from Baltimore, Maryland to Rochester, Michigan to Bloomington, Indiana and to Canton, Massachusetts, if required.

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

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.:

AUG 29 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, 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: GEC/DL