U.S. Department
of Transportation

**Research and
Special Programs
Administration**

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

DOT-E 10148 (EXTENSION)
ORIGINAL DECEMBER 12, 1991

In accordance with 49 CFR 107.113 of the Department of Transportation (DOT) Hazardous Materials Regulations (HMR), DOT-E 10148 is hereby extended for the party(ies) listed below by changing the expiration date in paragraph 10 to July 31, 1997. All other terms of the exemption remain unchanged.

This emergency extension, which will prevent serious economic loss applies only to the party(ies) listed below based on the application(s) received in accordance with 49 CFR 107.113. This emergency extension constitutes a necessary part of this exemption and must be attached to it. This emergency extension is not retroactive.

This emergency extension does not resolve proceedings which may be initiated by the Office of Chief Counsel, Research and Special Programs Administration concerning operations which occurred between November 30, 1993, and the issue date of this emergency extension, which were not in compliance with the HMR, and which were no longer authorized by any exemption.

Alan I. Roberts
Associate Administrator
for Hazardous Materials Safety

AUG 31 1995
(DATE)

Dist: FHWA FAA FRA USCG

EXEMPTION HOLDER	APPLICATION DATE
Pro-Tech-Tube, Inc. Kansas City, Missouri	August 31, 1995

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

DEC 12 1991

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

DOT-E 10148

1. Pro-Tech-Tube, Inc., Kansas City, Missouri, is hereby granted an exemption from certain provisions of this Department's Hazardous Materials Regulations to manufacture, mark, and sell the packaging described in paragraph 7 below for use in the transportation in commerce of an etiologic agent (infectious substance) described in paragraph 3 below subject to the requirements specified herein. This exemption authorizes the manufacture, marking, and sale of a packaging that does not pass the penetration impact test in 49 CFR 173.387(b)(2)(iii) but provides an equivalent level of safety for shipment of etiologic agents and provides no relief from any regulation other than as specifically stated.

2. BASIS. This exemption is based on Pro-Tech-Tube's application received March 20, 1989, and supplementary information dated September 8, 1989, October 24, 1989, January 21, 1991, March 7, 1991, November 8, 1991, and December 2, 1991, submitted in accordance with 49 CFR 107.103 and the public proceeding thereon.

3. HAZARDOUS MATERIALS (Descriptor and class). Etiologic agents (infectious substances), as prescribed in paragraph 7.b. below and limited to 50 milliliters (1.69 ounces) per package as specified therein; classed as Etiologic agent (or Infectious substance, as appropriate).

4. PROPER SHIPPING NAME (49 CFR 172.101). Etiologic agent, n.o.s.; or other generic description, as appropriate.

5. REGULATION AFFECTED. 49 CFR 173.387 (b)(2)(iii); (or 49 CFR 178.609(h)(1), as appropriate).

6. MODES OF TRANSPORTATION AUTHORIZED. Motor vehicle, rail freight, cargo vessel, passenger-carrying aircraft, and cargo aircraft only.

7. SAFETY CONTROL MEASURES.

a. Packaging prescribed is a combination packaging consisting of an inner packaging and an outer packaging in accordance with drawings submitted with the application. The inner packaging consists of a primary receptacle(s) and a secondary packaging. The secondary packaging consists of a sheet of fully reticulated, fine pore, flexible polyurethane foam and a three mil thick (minimum)

DEC 12 1991

polyethylene bag. The foam sheet is impregnated and coated with a biological detergent and will absorb, encapsulate and deactivate any material that might escape from the primary receptacle(s). The outer packaging is a tapered, cylindrical, removable head, plastic packaging with a flat base (drum) and a tamper evident closure. The etiologic agent is sealed in the primary receptacle. The primary receptacle is wrapped in the foam sheet and sealed in the polyethylene bag. More than one primary receptacle may be placed in the inner packaging. The foam sheet must completely surround and cushion the primary receptacle(s). The inner packaging is sealed in the outer packaging. The package must be capable of passing the penetration test from a height of 30 inches when tested in accordance wit 49 CFR 173.387(b)(2)(iii).

b. Material that may be transported in the packaging prescribed herein is restricted to body fluids and excretions, such as: blood, sweat, tears, tissue, semen, secretions, cerebrospinal fluid, amniotic fluid, feces, nasal secretions, sputum, urine, saliva, and breast milk.

c. The quantity of material is limited to 50 milliliters (1.69 ounces) per package.

8. SPECIAL PROVISIONS.

a. Offerors for transportation of hazardous materials specified in this exemption may use the packaging described in this exemption for the transportation of such hazardous materials so long as no modifications or changes are made to the packages, all terms of this exemption are complied with, and a copy of the current exemption is maintained at each facility from which such offering occurs.

b. In accordance with the provisions of 49 CFR Part 107, Appendix B to Subpart B, Paragraph 3, the shipper shall furnish a copy of this exemption to the air carrier before or at the time the shipment is tendered. In addition, a copy of this exemption must be carried aboard each aircraft, and cargo vessel used to transport packages covered by this exemption.

c. Shippers using the packaging covered by this exemption must comply with the shipping paper, marking, labeling, and placarding requirements of 49 CFR Part 172; all provisions of this exemption, and all other applicable requirements contained in 49 CFR Parts 100-180.

d. Each packaging manufactured under the authority of this exemption must be either (1) marked with the name of the manufacturer and location (city and state) of the facility at which it is manufactured or (2) marked with a

registration symbol designated for a specific manufacturing facility. In addition to the exemption number, DOT-E 10148, and any other required marking, the words "Restricted: Body Fluids And Excretions Only" shall be marked on the packaging. Also, packagings which have been tested in accordance with Chapter 9 of the UN Recommendations at the Packaging Group I level may be marked as follows: (the UN symbol for packagings) 1H2V/X.2/S/92/USA/M-XXXX.

e. A copy of this exemption, in its current status, must be maintained at each manufacturing facility at which this packaging is manufactured and must be made available to a DOT representative upon request.

9. REPORTING REQUIREMENTS. Any incident involving loss of packaging contents or packaging failure must be reported to the Associate Administrator for Hazardous Materials Safety as soon as practicable.

10. EXPIRATION DATE. November 30, 1993.

Issued at Washington, D.C.

December 13, 1991
(DATE)

Alan I. Roberts
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, Washington, D.C. 20590. Attention: Exemptions Branch.

Dist: USCG, FAA, FHWA, FRA.