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

NOV 9 2001

### DOT-E 12861

EXPIRATION DATE: January 31, 2002

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. <u>GRANTEE</u>: Micro-Med Industries, Inc. Jacksonville, FL

## 2. PURPOSE AND LIMITATION:

- a. This emergency exemption authorizes the transportation in commerce of solid materials contaminated with or suspected to be contaminated with anthrax bacteria or spores, in non-DOT specification bulk size outer packaging, for complete decontamination prior to disposal. 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. <u>REGULATORY SYSTEM AFFECTED</u>: 49 CFR Parts 106, 107 and 171-180.
- 4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 172.101 Table Column 8C in that bulk size outer packagings are not authorized for infectious substances, affecting humans, except as specified herein.
- 5. <u>BASIS</u>: This exemption is based on the application of Micro-Med Industries, Inc. dated November 1, 2001 and additional information dated November 6, 2001, submitted in accordance with § 107.117 and a determination that it is necessary to prevent significant injury to persons or property.

# 6. HAZARDOUS MATERIALS (49 CFR § 172.101):

| Proper Shipping Name/<br>Hazardous Materials Description                                 | Hazard<br>Class/<br>Division | Identi-<br>fication<br>Number | Packing<br>Group |
|--|------------------------------|-------------------------------|------------------|
| Infectious substances, affecting humans (anthrax - contaminated solid material) See Note | 6.2                          | UN2814                        | N/A              |

Note The infectious substances authorized under this exemption are limited to solid materials that have been or are suspected to have been contaminated with anthrax bacteria or spores and that have been treated by a chemical disinfectant, but may still pose a hazard.

# 7. <u>SAFETY CONTROL MEASURES</u>:

# a. <u>LIMITATIONS ON SOLID MATERIALS THAT HAVE POTENTIALLY</u> <u>BEEN CONTAMINATED WITH ANTHRAX</u>:

- (1) This exemption authorizes the transportation in commerce of solid materials that have been contaminated with or are suspected to have been contaminated with anthrax in a packaging system that consists of a bulk-size outer packaging (BOP) and non-bulk and bulk-sized inner packagings. The inner packagings are plastic bags conforming with paragraph 7.b.(2) of this exemption.
- (2) Inner packagings must be placed into the BOP in such a manner as to minimize the risk of breakage and be secured to prevent movement during transportation.
- b. <a href="PACKAGING">PACKAGING</a>: The following packaging system is authorized:
  - (1) Bulk Outer Packaging (Metal or Fiberglass) (BOP):
    - (i) The BOP must be of metal or fiberglass construction and have a capacity of at least 3.5 cubic meters (124 cubic feet) and not more than 45 cubic meters (1590 cubic feet) in volume. It must be leakproof and have interior surfaces that are smooth, non-porous and free of cracks, crevices and other defects that could damage inner packages or obstruct decontamination operations.

- (ii) The BOP must have bottom and side joints of fully welded or seamless construction and a rigid, weatherproof top that prevents the intrusion of water (e.q., rain or snow).
- (iii) Each opening in the BOP must be fitted with a closure that will prevent the intrusion of water and release of any liquid during all loading and transportation operations.
- (iv) In the upright position, the BOP must be liquid-tight at the bottom and able to contain a liquid quantity of at least 300 liters (80 gallons) with closures open.

#### Inner Packaging: (2)

- (i) The inner packaging authorized is a plastic film bag which must be a minimum of 3 mils in thickness and must be certified by its manufacturer as being capable of passing the tests prescribed for tear resistance in ASTM D 1922-94a, titled Propagation Tear Resistance of Plastic Film, and for impact resistance in ASTM D 1709-97, titled Test Method For Impact Resistance by the Free Falling Dart Test. Each plastic film bag must have an impact resistance of 165 grams and a tearing resistance of 480 grams in both the parallel and perpendicular planes with respect to the length of the bag.
- (ii) The inner packaging must be closed with a minimum of entrapped air and sealed securely by taping or tying the plastic to prevent the release of any material from the bag when inverted.

## c. <u>OPERATIONAL CONTROLS</u>:

- (1) Prior to placement of the solid material in the inner packaging: all sharp edges must be rounded or padded; and the material must be treated with a disinfectant that is recommended by the Centers for Disease Control and Prevention for use as a disinfectant for anthrax bacteria and spores.
- After the inner packaging is sealed, the exterior surface of the inner packaging must be treated with the disinfectant.

- (3) Prior to loading into the BOP, the inner packaging must be placed into a second plastic bag as specified in paragraphs 7.b.(2)(i) and (ii) above. After the second plastic bag is sealed, the exterior surface must be treated with the disinfectant.
- (4) Upon completion of delivery of the lading to its destination, the carrier must decontaminate the BOP with the disinfectant.

# 8. SPECIAL PROVISIONS:

- a. The outside of each BOP must be plainly and durably marked "DOT-E 12861" as specified in §§ 172.302(b) and (c).
- b. In addition to marking the required identification number on the BOP as specified in § 172.332, each side and each end must be marked "BIOHAZARD" in letters at least two inches high on a contrasting background.
- c. The carrier: may not drop off and leave a BOP at a loading point under the terms of this exemption; must transport a BOP containing lading to a final destination without unnecessary delay from the time the carrier loads the BOP onto the carrier's motor vehicle at the loading point; and may not leave the motor vehicle unattended.
- d. The motor vehicle must be dedicated to exclusive use for the transportation of solid materials that have been contaminated with or are suspected to have been contaminated with anthrax or spores and which have been treated with a disinfectant. No other ladings or packages may be combined on the vehicle with these materials.
- 9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle.
- 10. <u>MODAL REQUIREMENTS</u>: The carrier must keep a current copy of this exemption aboard each motor vehicle used to transport packages covered by this exemption.
- 11. <u>COMPLIANCE</u>: 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 <u>et seg</u>:

- 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 A. McGuire

Associate Administrator for Hazardous Materials Safety

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(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.

The original of this exemption is on file at the above office. Photo reproductions and legible reductions of this exemption are permitted. Any alteration of this exemption is prohibited.

Copies of exemptions may be obtained from the AAHMS, U.S. Department of Transportation, 400 7th Street, S.W., Washington, DC 20590-0001, Attention: Records Center, 202-366-5046.

PO: PTOlson