U.S. Department
of Transportation

**Research and
Special Programs
Administration**

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

DEC 5 2000

DOT-E 12541

EXPIRATION DATE: **November 30, 2002**

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: Rotonics Manufacturing, Inc.
Gardena, CA

2. PURPOSE AND LIMITATIONS:

a. This exemption authorizes the manufacture, marking, sale and use of high density polyethylene, rotationally molded, bins as outer packagings for the transportation in commerce of regulated medical waste, as defined in paragraph 7.a. below, in dual packagings. 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, including loading and unloading.

3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180. All sections referenced in this exemption are found in these Parts.

4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 172.101 Columns (8B) and (8C) for Regulated medical waste, and § 173.197 in that a non-DOT specification packaging is defined and authorized herein.

5. BASIS: This exemption is based on the application of Rotonics Manufacturing, Inc. dated August 18, 2000, submitted in accordance with § 107.105 and the public proceeding thereon.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

| Proper Shipping Name/ Hazardous Material Description | Hazard Class/ Division | Identi-fication Number | Packing Group |
|---|---|---|---|
| Regulated medical waste | 6.2 | UN3291 | II |

7. SAFETY CONTROL MEASURES:

a. LIMITATIONS ON REGULATED MEDICAL WASTE:

(1) This exemption authorizes the manufacture, marking, sale and use of a bulk outer packaging for the transportation of regulated medical waste, as defined in § 173.134(a)(4), in a packaging system which consists of a bulk outer packaging - caster cart (Cart) used exclusively for medical waste, and non-bulk inner packagings. The inner packaging may be a plastic film bag conforming to paragraph 7.b.(2) of this exemption or a rigid packaging conforming to the requirements of § 173.197.

(2) Only solid regulated medical waste may be transported in the plastic film bags described in paragraph 7.b.(2) below. No free liquids are authorized. Waste material containing absorbed liquid may be packaged as a solid in a plastic film bag if the bag contains sufficient absorbent materials to absorb and retain all liquid during transportation.

(3) Division 6.1 toxic waste and Class 7 radioactive waste, with the exception of those materials that are chemotherapeutic waste, may not be transported under this exemption. Division 6.1 and Class 7 chemotherapeutic waste may be transported under this exemption in accordance with paragraph 8.b.

(4) Untreated cultures and stocks of infectious substances at Biosafety Level 4, as defined in HHS Publication No. (CDC) 93-8395, Biosafety in Microbiological and Biomedical Laboratories, 3rd Edition, May 1993, Section II, may not be transported under this exemption.

(5) Sharps containers may be transported under this exemption in accordance with paragraph 8.b.

b. PACKAGING: The following packaging system is authorized:

(1) Bulk Outer Packaging - caster cart (Cart): The Cart must be a solid, one-piece, leakproof, body with a nominal volume not to exceed 1655 L (364 gallons). It must have interior surfaces that are smooth, non-porous and free of cracks, crevices and other defects which could damage inner packages or obstruct decontamination operations. The Cart must have a lid which is gasketed or forms a seal when closed and is mounted on at least 4 casters.

(2) Inner Packaging:

(i) A plastic film bag used under this exemption 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) Inner packagings must be durably marked or tagged with the name, city and state location of the offeror.

c. RESPONSIBILITIES OF CARRIER:

(1) If the carrier is the owner of the Cart, the carrier must provide to the manufacturer a written certification as specified in paragraph 8.a. that the carrier understands and accepts the responsibil-ities of a carrier as specified in paragraph 7.c. Such carrier must provide a copy of this exemption to each person from whom the carrier intends to accept

regulated medical waste for transportation under this exemption, and the carrier must obtain and retain from each such offeror of regulated medical waste a written certification that the offeror understands and accepts the responsibilities of an offeror as specified in paragraph 7.d.

(2) Prior to transporting regulated medical waste, the carrier must perform an external visual inspection of the transport vehicle to determine that it is closed and free of leakage.

(3) Prior to providing a Cart for reuse, the carrier must decontaminate the Cart with a disinfectant that is registered with the U.S. Environmental Protection Agency (EPA) for use as a disinfectant. A list of registered disinfectants may be obtained from EPA by calling 1-800-447-6349.

(4) The carrier must provide a Cart that meets the requirements of paragraph 7.(b).1 and assure that the Cart is used exclusively for transporting medical waste.

(5) The carrier must transport a vehicle loaded with one or more Carts containing regulated medical waste to a final destination that is authorized by applicable laws for storage, treatment or disposal of such wastes, without unnecessary delay from the time the carrier's motor vehicle leaves the offeror's premises.

(6) Transport vehicles may deliver decontaminated Carts for reuse. If a transport vehicle is used to deliver and pick up Carts at multiple locations on a single trip, the carrier must have a loading plan that keeps empty Carts for reuse segregated from Carts containing regulated medical waste.

(7) The carrier must have a written spill response plan that includes provisions for the decontamination of spilled materials and for personal protective equipment to be carried on the vehicle and used to protect its employees from contact with infectious materials in any form.

(8) The carrier must respond to any release from a Cart that occurs during its transportation, including its unloading from the vehicle. The response must include complete removal of any spilled material and decontamination of the release site, vehicle surfaces and external surfaces of the Cart involved.

(9) As required by paragraph 12 of this exemption, the carrier must report any release of any material from the Cart during its transportation (including the unloading of the Cart off of the carrier's motor vehicle). The unloading or emptying of the contents of the Cart at a storage, treatment or disposal facility does not constitute a release under this paragraph.

d. RESPONSIBILITIES OF OFFERORS:

(1) If the owner of the Cart is the offeror, the offeror must provide to the manufacturer a written certification as specified in paragraph 8.a. that the offeror understands and accepts the responsibilities of an offeror as specified in paragraph 7.d. Such offeror must provide a copy of this exemption to each carrier that transports regulated medical waste under this exemption, and the offeror must obtain and retain from each such carrier of regulated medical waste a written certification that the carrier understands and accepts the responsibilities of a carrier as specified in paragraph 7.c. A person who offers a regulated medical waste (e.g., a hospital or clinic that generates regulated medical waste) must comply with all applicable requirements of the HMR except as provided by this exemption.

(2) The offeror must maintain a current copy of this exemption at each location where the regulated medical waste is offered for transportation (disposal).

(3) The offeror's signature on the certification required on a shipping paper serves as affirmation of compliance with the terms of this exemption. The requirements for a shipping paper are contained in §§ 172.200 - 172.204.

(4) No package containing materials prohibited by paragraph 7.a. of this exemption may be offered for transportation under this exemption.

(5) When filled, a plastic film bag may not weigh more than 10 kg (22 lbs).

(6) Plastic film bags must be closed with a minimum of entrapped air and sealed by twisting the bag at the top and taping or tying the twist to prevent the release of any material from the bag when it is inverted.

(7) Inner packagings must be placed into the Cart in such a manner as to minimize the risk of breakage.

(8) During all times that a Cart is at the offeror's premises, and not under the carrier's direct control, the Cart is the responsibility of the offeror. The hinged lid on the Cart must be closed except when regulated medical waste is being loaded into the Cart.

(9) During all times that a truck or trailer is parked at the offeror's premises, and not under the carrier's direct control, the truck or trailer is the responsibility of the offeror. The doors on the vehicle must be closed except when regulated medical waste is being loaded into the vehicle.

(10) Before loading the Cart into a transport vehicle, the offeror must assure that the Cart is closed and sealed to prevent the release of any material during transportation.

(11) The offeror must load each Cart containing regulated medical waste into the transport vehicle in accordance with the carrier's instructions.

(12) The offeror must have a written spill response plan that provides for the decontamination of spilled materials and for personal protective equipment to be used to protect its employees from contact with infectious materials in any form.

(13) The offeror must respond to any release from a Cart that occurs during its loading into the carrier's transport vehicle. The response must include complete removal of any spilled material and decontamination of the release site, vehicle surfaces and external surfaces of the Cart involved.

e. TESTING - The Cart must be capable of meeting the requirements of §§ 178.603 (drop test) and 178.606 (stacking test), as specified for solids at the Packing Group II performance level.

8. SPECIAL PROVISIONS:

a. The manufacturer who is the holder of this exemption must provide a copy of this exemption to each person who buys any Cart marked with this exemption number. The manufacturer must obtain and retain from each such purchaser of a Cart for transporting regulated medical waste, a written certification that the purchaser understands and accepts the responsibilities of either a carrier as specified in paragraph 7.c. or an offeror as specified in paragraph 7.d., as applicable.

b. Chemotherapeutic waste, untreated stocks and cultures of infectious substances at Biosafety Level 1, 2 and 3, unabsorbed liquids, and sharps (e.g., glass, needles, or other sharp objects) may be transported in a Cart only if packaged in rigid non-bulk packagings as prescribed in the HMR (See §§ 173.134, 173.196 and 173.197).

c. MARKING: The carrier must plainly and durably mark the outside of each Cart with "DOT-E 12541" and with identification numbers in the manner specified for a bulk packaging in §§ 172.302(b), (c) and 172.331.

d. In accordance with the provisions of Paragraph (b) of § 173.22a, persons may use the packaging authorized by this exemption for the transportation of the hazardous materials specified in paragraph 6, only in conformance with the terms of this exemption.

e. A person who is not a holder of this exemption, but uses a package covered by this exemption, may offer it for transportation provided no modification or change is made to the package and it is offered for transportation in conformance with this exemption and the HMR.

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

g. 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 by the Office of Hazardous Materials Exemptions and Approvals for a specific manufacturing facility.

h. A current copy of this exemption must be maintained at each facility where the package is manufactured under this exemption. It must be made available to a DOT representative upon request.

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle.

10. MODAL REQUIREMENTS:

a. The carrier must keep a current copy of this exemption aboard each motor vehicle used to transport packages covered by this exemption. The exception in § 173.134(b)(3)(ii) does not apply to waste transported under the authority of this exemption.

b. Carts containing regulated medical waste as authorized by this exemption must be transported by a private or contract carrier in a transport vehicle dedicated to the service of hauling waste materials only. Each transport vehicle must be decontaminated after each delivery of regulated medical waste, prior to any loading of decontaminated carts for reuse.

11. COMPLIANCE:

a. Failure by a person to comply with the terms and conditions prescribed in this exemption and the HMR may result in modification, suspension or termination of this exemption and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq.

b. 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.

c. 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.

d. The offering and transportation of regulated medical waste in a packaging authorized by this exemption is not subject to the registration and fee requirements of Subpart G of 49 CFR Part 107.

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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 also inform the AAHMS, in writing, as soon as practicable of any incidents involving the package and shipments made under this exemption.

Issued in Washington, D.C.

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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.

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.

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