U.S. Department
of Transportation

**Research and
Special Programs
Administration**

DEC 19 2000

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

DOT-E 12533

EXPIRATION DATE: **December 31, 2002**

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: Adams Healthcare Ltd.
Leeds, England
(U.S. Agent: STERIS Corporation, St. Louis, MO)

2. PURPOSE AND LIMITATION:

a. This exemption authorizes the transportation in commerce of certain DOT 2Q containers containing aerosols. The containers have been tested by an alternative method in lieu of the hot water bath test. 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. The safety analyses did not consider the hazards and risks associated with consumer use or other uses not associated with transportation in commerce.

3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.

4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 173.306(a)(3)(v) in that the prescribed hot water bath test is replaced by an alternative test method.

5. BASIS: This exemption is based on the application of Adams Healthcare Ltd. dated August 8, 2000 submitted in accordance with § 107.105 and the public proceeding thereon.

6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Proper Shipping Name/ Hazardous Materials Description	Hazard Class/ Division	Identi- fication Number	Packing Group
Aerosols	2.1	UN1950	N/A

7. SAFETY CONTROL MEASURES:

a. PACKAGING - Packaging prescribed is a DOT Specification 2Q container. Each container, as filled for shipment must be contained within three polyethylene bags, each one inside the other, each individually hermetically heat-sealed. Each container must meet all requirements of § 173.306(a)(3) except for the hot water bath test requirements specified in § 173.306(a)(3)(v).

b. TESTING -

(1) Each container, after it is bagged and sealed, must be irradiated at not less than 25 KGy so that the container contents are heated to at least 86°F. Each bag must be visually inspected for signs of leakage of the container. Containers that show leakage or deformation must not be shipped.

(2) One container out of each batch of 300 containers filled for shipment must be hot water bath tested. The temperature of the bath and the duration of the test must be such that the internal pressure reaches that which would be reached at 122°F. Any leakage or deformation of the container tested will be cause for the batch to be rejected. Three more containers from the same batch, constituting a second batch test, may be tested. Only if each of the three containers passes the hot water bath test, without leakage or deformation, may the batch be shipped.

c. OPERATIONAL CONTROLS - Prescribed containers may be shipped under the provisions of § 173.306(a).

8. SPECIAL PROVISIONS:

a. A person who is not a holder of this exemption who receives a package covered by this exemption may reoffer it for transportation provided no modifications or change are made to the package and it is reoffered for transportation in conformance with this exemption and the HMR.

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

c. MARKING -

(1) Each container must be marked "DOT-E 12533".

(2) Each outside packaging must be marked "INSIDE CONTAINERS COMPLY WITH DOT-E 12533".

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle and cargo vessel.

10. MODAL REQUIREMENTS: There are no modal specific requirements associated with 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.:

Robert A. McGuire
Acting Associate Administrator for
Hazardous Materials Safety

DEC 19 2000
(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: cwf