

April 24, 2007



U.S. Department
of Transportation

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

**Pipeline and Hazardous
Materials Safety Administration**

DOT-SP 13422
(FIRST REVISION)

EXPIRATION DATE: March 31, 2011

(FOR RENEWAL, SEE 49 CFR § 107.109)

1. GRANTEE: Puritan Bennett
Plainfield, IN

2. PURPOSE AND LIMITATION:

a. This special permit authorizes the transportation in commerce of a non-DOT specification cylinder that is a component of a portable medical unit containing oxygen, refrigerated liquid (portable unit) and authorizes use of such portable units on board passenger-carrying aircraft. This special permit provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein. Nothing in is this special permit waives or supersedes any requirement or prohibition by an airline, or other governmental agency regarding transportation of the portable unit on a passenger-carrying aircraft.

b. The safety analyses performed in development of this special permit only considered the hazards and risks associated with transportation in commerce.

c. Nothing in is this special permit supersedes any requirement of another federal agency to obtain an approval, waiver, or other authorization for use of the HELIOS portable device. Operating requirements of the Federal Aviation Administration (14 CFR 121.574(a)(1)(iii)) stipulate that equipment for the storage, generation, or dispensing of oxygen must be maintained by the relevant air carrier's (certificate holder) approved maintenance program. Persons using this special permit should consult their air

carrier to determine if this device is authorized for use by passengers.

c. Party status will not be granted to this special permit.

3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR § 172.101(9A) in that carriage of oxygen, refrigerated liquid is forbidden on passenger-carrying aircraft; and §§ 173.316 and 175.3 in that the transport of a non-DOT specification cylinder is not authorized except as specified herein.
5. BASIS: This special permit is based on the application of Puritan Bennett dated April 1, 2007 submitted in accordance with § 107.109.
6. HAZARDOUS MATERIALS (49 CFR § 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identification Number	Packing Group
Oxygen, refrigerated liquid (cryogenic liquid)	2.2	UN1073	N/A

7. SAFETY CONTROL MEASURES:
 - a. PACKAGING - Packaging prescribed is a non-DOT specification insulated cylinder that is a component of the Puritan Bennett HELiOS PPM-1 (Models H-300 and H-300 Plus) liquid oxygen system. The liquid oxygen system must meet the requirements of the Mallinckrodt Verification Test Summary Report for PPM-1 HELiOS Small Portable unit dated 1/19/00 and Puritan Bennett Validation Test Summary Report for HELiOS H-300 Portable dated 4/15/01 on file with the Office of Hazardous Materials Special Permits and Approvals (OHMSPA). The non-DOT specification cylinder must conform with the DOT 4L Specification (§§ 178.35 and 178.57) except as follows:

§ 178.57 (a) Type, size, service pressure and design service temperature.

- (1) Type and size. Must be fusion welded. Water capacity may not exceed one pound.
- (2) Service pressure. May not exceed 22 psig.
- (3) Design service temperature. Must be -320°F or colder.

§ 178.57(d) Manufacture.

* * * * *

(2) * * * The heads of the cylinder must be torispherical.

(3) * * * except the sixth sentence is deleted and the fifth sentence is replaced with the following:

"The construction must be such that the total heat transfer from the atmosphere at ambient temperature to the cylinder lading may not exceed 0.200 Btu per hour per °F temperature differential per pound of water capacity of the cylinder, but not to exceed 2.0 pounds of evaporated oxygen, refrigerated liquid oxygen per day.

§ 178.57(h) Openings in Cylinder.

- (1) * * * except a 3/16" diameter tube is authorized to be fusion welded or brazed directly to each head. Brazing must be in accordance with Puritan Bennett procedure: Manual Brazing SPI 294 on file with the OHMSPA.

§ 178.57(p) Marking.

Applies, except that the outside of each portable unit must be marked "DOT-SP 13422" in letters at least 0.25 inch high on a contrasting background.

b. TESTING -

(1) Puritan Bennett must certify each portable unit authorized by this special permit. Each portable unit must be leak tested at test pressure and visually inspected in accordance with the requirements of Puritan Bennett document H-300 Service Repair, Stations 1 through 6 on file with the OHMSPA.

(i) The inspection must be: documented on a Service Repair Form maintained by Puritan Bennett; and available to a DOT representative upon request.

(ii) A certification decal must be placed on the outside of each portable unit which will be used on a passenger-carrying aircraft. The decal must include as a minimum, the serial number of the unit and the expiration date of the certification. The expiration date may not exceed 90 days from the date the inspection is performed.

(2) Any portable unit determined to be leaking or damaged must be repaired and successfully leak tested before being returned to service.

c. OPERATIONAL CONTROLS - Puritan Bennett must provide instruction in the proper use of the portable unit and a written copy of the manufacturer's instructions to each patient on the proper use of the portable unit on a passenger-carrying aircraft. Prior to use of this special permit, a current copy of the manufacturer's instructions must be on file with OHMSPA. At a minimum, the following information must be included in the instructions:

(1) The special permit number.

(2) Methods to prevent the accumulation of oxygen in the cabin, such as by turning off the oxygen supply valve when the portable unit is not being used.

(3) A warning against carrying the portable unit under a coat or any form of clothing and a statement that the portable unit must be visible at all times.

(4) A warning to keep all flammable materials away from the portable unit.

- (5) A warning to keep all portable units out of the reach of children.
- (6) A warning that no unauthorized individuals shall be allowed to tamper with the portable unit.
- (7) A warning to keep oils, greases, Vaseline, lotions, facial creams, and hair dressings away from the systems. Aerosol sprays are also prohibited from use in the vicinity of the systems.
- (8) Notification that only one portable unit may be transported by a passenger on a passenger-carrying aircraft.
- (9) A notification that the portable unit may not be refilled during transportation.
- (10) Instructions on the necessary safeguards and proper procedures to be followed in the event of fire or accident involving the portable unit.

8. SPECIAL PROVISIONS:

- a. A person who is not a holder of this special permit who receives a package covered by this special permit may reoffer it for transportation provided no modification or change is made to the package or its contents and it is reoffered for transportation in conformance with this special permit and the HMR.
- b. A current copy of this special permit and the manufacturer's instructions must be maintained at each manufacturer and distributor facility where the portable unit is offered or reoffered for transportation or provided to patients.
- c. Airline personnel must be provided instructions on the necessary safeguards and proper procedures to be followed in the event of fire or accident involving the portable unit.

d. Each passenger may carry only one portable unit aboard passenger-carrying aircraft. Additional portable units or replacement units are not authorized. The portable unit may only be used by a passenger in need of oxygen, provided the passenger has, in their immediate possession, a current copy of manufacturer's instructions (see paragraph 8.h.) for portable unit and is knowledgeable in the proper use of the portable unit.

e. A portable unit may not be placed in an overhead compartment of a passenger-carrying aircraft cabin or in a checked baggage compartment.

f. A portable unit used under this special permit may not have any outstanding recall notices.

g. In addition to the above, the following provisions apply. The requirement for a doctor's documentation of proof for need for medical oxygen by a passenger may be required by the airline at their discretion. Airlines must be notified in advance of the intent to bring the portable unit on a passenger aircraft.

h. A portable unit may not be offered or transported on a passenger-carrying aircraft after the expiration date indicated on the manufacturer's certificate on the portable unit.

i. Nothing in is this special permit waives or supersedes any requirement or prohibition by an airline, or other governmental agency regarding transportation of the portable unit on a passenger-carrying aircraft.

j. Packagings permanently marked 'DOT-E 13422', prior to October 1, 2007 may continue to be used under this special permit for the remaining service life of the packaging or until the special permit is no longer valid. Packagings marked on or after October 1, 2007 must be marked 'DOT-SP 13422'.

k. Shipping papers displaying 'DOT-E 13422' may continue to be used until October 1, 2007, provided the special permit remains valid.

9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle and passenger-carrying aircraft.

10. MODAL REQUIREMENTS:

a. A current copy of this special permit must be carried aboard each aircraft or motor vehicle used to transport packages covered by this special permit. Puritan Bennett may provide the air carrier a current copy of the special permit or the air carrier may obtain a current copy of the special permit at http://hazmat.dot.gov/sp_app/special_permits/spec_perm_index.htm

b. Drivers must have been instructed as to necessary safeguards and proper procedures in the event of unusual delay, fire, or accident.

11. COMPLIANCE: Failure by a person to comply with any of the following may result in suspension or revocation of this special permit and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 et seq:

- o All terms and conditions prescribed in this special permit and the Hazardous Materials Regulations, 49 CFR Parts 171-180.
- o Persons operating under the terms of this special permit must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
- 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 special permit must receive training on the requirements and conditions of this special permit in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this special permit, including display of its number, when this special permit has expired or is otherwise no longer in effect.

Under Title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU)- 'The Hazardous Materials Safety and Security Reauthorization Act of 2005' (Pub. L. 109-59), 119 Stat. 1144 (August 10, 2005), amended the Federal hazardous materials transportation law by changing the term 'exemption' to 'special permit' and authorizes a special permit to be granted up to two years for new special permits and up to four years for renewals.

12. REPORTING REQUIREMENTS: Shipments or operations conducted under this special permit are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 - Immediate notice of certain hazardous materials incidents, and 171.16 - Detailed hazardous materials incident reports. In addition, the grantee(s) of this special permit must notify the Associate Administrator for Hazardous Materials Safety, in writing, of any incident involving a package, shipment or operation conducted under terms of this special permit.

Issued in Washington, D.C.:



for Bob Richard
Deputy Associate Administrator
for Hazardous Materials Safety

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration, Department of Transportation, Washington, D.C. 20590. Attention: PHH-31.

Copies of this special permit may be obtained by accessing the Hazardous Materials Safety Homepage at http://hazmat.dot.gov/sp_app/special_permits/spec_perm_index.htm Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

PO: CWFreeman:sln