



U.S. Department of Transportation  
**Pipeline and Hazardous Materials  
Safety Administration**

APR 20 2011

1200 New Jersey Ave, SE  
Washington, D.C. 20590

Mr. Richard W. Boerdner  
Production Manager  
AirSep Corporation  
401 Creekside Drive  
Buffalo, NY 14228-2085

Reference No. 11-0072

Dear Mr. Boerdner:

This responds to your March 25, 2011 letter and subsequent telephone conversation with a member of my staff regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) to a portable oxygen concentrator (POC) for purposes of obtaining FAA approval to allow a passenger to carry the POC aboard an aircraft. According to your letter, the POC (trade name Focus) is a device that separates oxygen from ambient air through a process called Pressure Swing Absorption (PSA). The device uses oxygen conserving technology to provide supplemental oxygen to persons with medical needs. The maximum operating pressure of the POC is 39 psia at 20 °C. The POC is powered by multiple sources, including AC or DC power, and a rechargeable lithium-ion battery pack. The battery pack consists of four 2.6 Ah lithium-ion cells equating to an equivalent lithium content of 0.78 g per cell and 3.12 g aggregate equivalent lithium content for the battery pack (38.48 Wh). The lithium-ion battery pack is a type proven to meet the appropriate tests in the United Nations Manual of Tests and Criteria, and the battery pack is packaged in a manner to prevent short circuits when offered for transport or carried onboard passenger aircraft. You ask whether this device is regulated under the HMR.

Based on the information provided in your letter, the Focus POC is currently not subject to the HMR because: (1) the pressure of the oxygen in the device does not exceed 200 kPa gauge (29.0 psig/43.8 psia) at 20 °C (68 °F); (2) the lithium-ion battery pack used to operate the device is excepted from the HMR under § 172.102(c)(1), Special provision 188; (3) the POC contains no other materials subject to the HMR; and (4) the battery pack is packaged in a manner to preclude it from creating sparks or generating a dangerous quantity of heat (e.g., by the effective insulation of exposed terminals).

Although the exception in § 175.10(a)(18) of the HMR would apply to a passenger carrying a Focus POC as described above, approval by the Federal Aviation Administration (FAA) is required before it may be used by a passenger onboard an aircraft. The FAA published a final rule on July 12, 2005 (70 FR 40155) regarding these devices. For further assistance, you may contact Mr. Dave Catey, Aviation Safety Inspector for the FAA Air Carrier Operations Branch (AFS-220) by phone at (202)-267-3732 or email at [david.catey@faa.gov](mailto:david.catey@faa.gov). In addition, even with

FAA approval, an air carrier ultimately determines what may or may not be carried on its aircraft. We suggest that you contact the airlines to ensure that the Focus POC may be carried.

I trust this satisfies your inquiry. Please contact us if we can be of further assistance.

Sincerely,

A handwritten signature in black ink that reads "Ben Supko". The signature is written in a cursive style with a long, sweeping tail on the "o".

Ben Supko  
Acting Chief, Standards Development Branch  
Standards and Rulemaking Division



Industrial & Medical Air Separation Equipment

AirSep Corporation  
401 Creekside Drive  
Buffalo, New York 14228-2085  
(716) 691-0202  
Fax (716) 691-4141

March 25, 2011

Mr. Charles Betts  
U.S. DOT  
PHMSA Office of Hazardous Materials Standards  
Attention: PHH-10  
East Building  
1200 New Jersey Avenue, SE.  
Washington, DC 20590-0001

Der Kinderen  
§173.115  
§175.10,  
Classification  
11-0072

**Subject: Formal Letter of Interpretation**

Dear, Mr. Betts

In accordance with 49 CFR 173.115, after review of this section of the CFR it is our interpretation that our Focus portable oxygen concentrator manufactured by AirSep Corporation in Buffalo New York is exempt as hazardous materials. However we would like your offices concurrence to our interpretation.

Our complete contact Information is as follows:

AirSep Corporation  
401 Creekside Drive  
Buffalo, New York 14228  
Attn: Richard W. Boerdner -- Production Manager - POC  
716 691-0202 ext. 365  
[rboerdner@airsep.com](mailto:rboerdner@airsep.com)

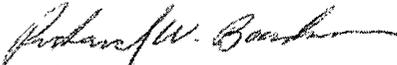
The device for which an exemption is being considered is a portable oxygen concentrator known by the trade name of Focus. People who have a medical condition that requires them to receive supplemental oxygen therapy use this device as a source of oxygen. The Focus portable oxygen concentrator separates oxygen from ambient air through a process called Pressure Swing Adsorption (PSA). This portable oxygen concentrator uses oxygen conserving technology. The systems maximum operating pressure is 39 psia at 20° C. The device uses multiple power sources, including AC or DC power and rechargeable lithium ion battery which is a 2.6 Ah, 38.48 Wh battery pack. The lithium ion cells and battery pack are compliant to the United Nations Manual of Tests and Criteria and is packaged in a manner to prevent short circuits when offered for transport or carried on board passenger aircraft.

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AirSep Corporation requests your office concurrence that our Focus is exempt from section 175.10 paragraph A18 which allows a certificate holder to allow passengers to carry and operate such devices provided a number of conditions are met. AirSep Corporation is not a certificate holder however we do have procedures in place to ensure the safety and effectiveness of the Focus. These include the requirements of the FDA's GMP (Good Manufacturing Practices), International standards IEC 60601-1 General requirements for safety for Medical equipment, and IEC 60601-1-2 for Electromagnetic compatibility requirements and tests for medical equipment. In addition the AirSep Quality Management System is approved as being compliant with the requirements of ISO9000:2000 and ISO 9000:13485 guideline with no exclusions.

I look forward to your review and input on exemption of this product. If you should need any more information please feel free to contact me.

Sincerely,



Richard W. Boerdner  
Production Manager - POC  
AirSep Corporation