



U.S. Department
of Transportation

**Pipeline and
Hazardous Materials Safety
Administration**

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

JUN 30 2006

Mr. Richard W. Boerdner
Product Manager / FreeStyle
AirSep Corporation
260 Creekside Drive
Buffalo, NY 14228

Ref. No.: 06-0061

Dear Mr. Boerdner:

This is in response to your March 6, 2006 letter and subsequent telephone conversation with Arthur Pollack of my staff regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 100-180) to a device that your company calls the FreeStyle portable oxygen concentrator.

Based on the information provided, the FreeStyle portable oxygen concentrator is not currently subject to the HMR because it meets the following criteria:

- (1) the pressure of the oxygen in the device does not exceed 40.6 psia at 20 °C;
 - (2) the lithium ion battery used to operate the device is excepted from the HMR (§ 173.185(c)(2));
 - (3) the portable oxygen concentrator 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 (for example, by the effective insulation of exposed terminals).

In accordance with the 2005-2006 Edition of the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air, your device is regulated as a Class 9 material when transported as cargo onboard passenger and cargo aircraft. However, the device may be authorized in baggage onboard passenger aircraft as consumer electronic devices containing lithium ion batteries with up to 25 grams of equivalent lithium content when carried by passengers or crew for personal use and protected so as to prevent short circuits.

In addition, Federal Aviation Administration (FAA) approval is required before these electronic devices are used by passengers on board aircraft. The FAA published a final rule in the Federal Register regarding these devices on July 12, 2005 (70 FR 40156).



060061

173.185(c)(2)
173.115
173.10

You may be interested to know that, in a notice of proposed rulemaking published under Docket HM-224C on April 2, 2002 (67 FR 15510), the Pipeline and Hazardous Materials Safety Administration has proposed to eliminate the 25-gram exception for lithium batteries found under § 173.185(c)(2) of the HMR. Please refer to our website at <http://hazmat.dot.gov> under the Rules and Regulations icon, in the rulemaking and Federal Register Notices section.

I hope this information is helpful. If you have further questions, please do not hesitate to contact this office.

Sincerely,

A handwritten signature in cursive script, appearing to read "Hattie L. Mitchell". The signature is written in black ink and is positioned above the typed name.

Hattie L. Mitchell
Chief, Regulatory Review and Reinvention
Office of Hazardous Materials Standards



Industrial & Medical Air Separation Equipment

Pollack
§ 173.115
§ 175.10
AirAirSep Corporation
260 Creekside Drive
Buffalo, New York 14228-2075
(716) 691-0202
Fax (716) 691-1255

06-0061

March 6, 2006

Pipeline and Hazardous Material Safety Administration
Mr. Edward Mazzullo
PHH-10
U. S. Department of Transportation
Office of Hazardous Standards
400 7th Street, SW
Washington, DC 20590-0001
Fax: (202) 366-3012

Subject: Hazardous Materials Exemption

Dear, Mr. Edward Mazzullo

In accordance with 49 CFR 173.115, after review of this section of the CFR and my conversation with Ms. Diane Lavalley it is our interpretation that our FreeStyle 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
260 Creekside Drive
Buffalo, New York 14228
Attn: Richard W. Boerdner – Product Manager / FreeStyle
716 691-0202 ext. 365
rboerdner@airsep.com

The device for which an exemption is being considered is a portable oxygen concentrator known by the trade name of FreeStyle. People who have a medical condition that requires them to receive supplemental oxygen therapy use this device as a source of oxygen. When traveling onboard commercial aircraft, carriers currently supply these individuals with high-pressure cylinders as a source of this oxygen. AirSep Corporation believes that our portable oxygen concentrator could provide a safe cost effect alternative to the present supply means.

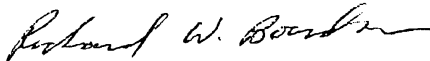
An oxygen concentrator separates oxygen from room air for delivery to the user.

Page 2

AirSep Corporation requests your office concurrence that our FreeStyle is exempt from section 175.10 paragraph A7 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 FreeStyle. These include the requirements of the FDA's GMP (Good Manufacturing Practices), International standards IEC 60101-1 General requirements for safety for Medical equipment, and IEC 60101-1-2 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 guideline with no exclusions.

To help you understand the concentrator, I am attaching an operational description, a process schematic, pressure profile graphs, and component drawings for your review. 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
AirSep Corporation