



U.S. Department  
of Transportation

**Pipeline and  
Hazardous Materials Safety  
Administration**

NOV 30 2005

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

Ms. Pamela J. Jackson  
Director of Marketing  
SeQual Technologies, Inc.  
11436 Sorrento Valley Road  
San Diego, CA 92121

Reference No.: 05-0215

Dear Ms. Jackson:

This is in response to your August 30, 2005 letter regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 100-180) to a device that your company calls the Eclipse Oxygen System.

You state in your letter that the Eclipse Oxygen System is a device that separates oxygen from ambient air for delivery to patients who require supplemental oxygen therapy. This device consists of a lightweight, portable oxygen concentrator with an integrated oxygen delivery valve for continuous flow or pulse delivery. The process by which oxygen is separated is called Pressure Swing Absorption (PSA). The maximum pressure of the oxygen exerted within the Eclipse Oxygen System packaging is 23.7 psia during normal operation at 20 °C. The device can be powered by multiple power sources, including AC or DC power, an AC adapter, rechargeable lithium ion batteries, and an automobile cigarette lighter adapter. The battery pack consists of 24, 2.2 ampere-hour lithium ion cells, and the total equivalent lithium content of the battery pack is 15.8 grams. The lithium ion battery pack has been tested pursuant 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 onboard passenger aircraft. You ask whether this device is regulated as a hazardous material under the HMR.

Based on the information provided, the Eclipse Oxygen System portable oxygen concentrator is not currently subject to the HMR because: (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 for transportation onboard passenger aircraft as consumer electronic devices containing lithium ion



050215

173.115  
173.185  
175.10

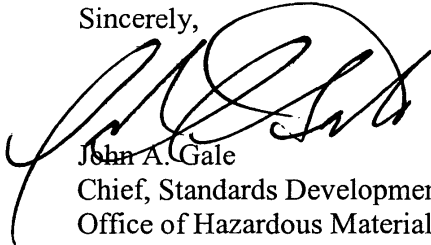
batteries with up to 25 grams of equivalent lithium content when carried by passengers or crew for personal use and protected so as to prevent short circuits.

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).

You may be interested to know that, in a notice of proposed rulemaking published under Docket HM-224E on December 15, 2004 (69 FR 75207), 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 [hazmat.dot.gov](http://hazmat.dot.gov) under the Rules and Regulations icon, in the rulemaking and Federal Register Notices section.

I trust this satisfies your inquiry.

Sincerely,

A handwritten signature in black ink, appearing to read "John A. Gale", is written over the typed name and title.

John A. Gale  
Chief, Standards Development  
Office of Hazardous Materials Standards



SeQual Technologies Inc.  
 11436 Sorrento Valley Rd. • San Diego, CA 92121-1306 • 858/202-3100 • FAX 858/558-1915

Foster  
 § 173.115  
 § 173.185  
 § 175.10  
 Applicability  
 05-0215

August 30, 2005

Mr. John Gale  
 Chief, Standards Development  
 Office of Hazardous Materials Standards  
 Pipeline and Hazardous Materials Safety Administration  
 U.S. Department of Transportation  
 400 Seventh Street SW  
 Washington, DC 20590-0001

Re: Classification of SeQual Technologies' Eclipse™ Oxygen System

Dear Mr. Gale:

Thank you very much for taking the time on the phone and allowing me to speak with you regarding SeQual Technologies' portable oxygen concentrator (POC) device known as the Eclipse™ Oxygen System. I am writing to request written confirmation from the Pipeline and Hazardous Materials Safety Administration (PHMSA) that the Eclipse™ Oxygen System is not subject to the U.S. hazardous materials regulations (HMR).

Background

The SeQual Eclipse Oxygen System is a device that separates oxygen from ambient air through a process called Pressure Swing Adsorption (PSA). The concentrated oxygen is used for delivery to patients with Chronic Obstructive Pulmonary Disease (COPD) that require supplemental oxygen therapy. The Eclipse provides a solution to address both stationary and portable requirements for oxygen patients having prescriptions of up to 3 LPM full flow operation and up to 6 LPM flow in a pulse flow mode operation. It consists of a lightweight, portable oxygen concentrator with an integrated oxygen delivery valve for continuous flow or pulse delivery and is capable of being operated directly from an AC or DC power source or from rechargeable lithium ion batteries. It can be recharged and/or powered by a separate AC adapter for use by the patient or where standard AC line power is available. The DC power adapter accessory allows power to be provided by a DC auxiliary power outlet, such as in a motor vehicle during transportation. User changeable battery packs are available to provide a range of ambulatory operational time.

The Eclipse Oxygen System achieves its performance through SeQual's patented Advanced Technology Fractionator (ATF®) technology and patented variable

speed compressor and compressor drive, advanced molecular sieve materials and rechargeable batteries. This system will expand an oxygen patient's ability to travel via aircraft and improve the patient's quality of life.

Class 2, Division 2.2 Gas – 49 CFR 173.115

The maximum pressure of the oxygen exerted within the Eclipse Oxygen System packaging currently is 23.7 psia during normal operation at 20° C. This is substantially less than the 40.6 psia at 20° C referenced in 49 CFR 173.115(b)(1) for defining a Division 2.2 gas. Therefore, it is our opinion that the oxygen exerted within the Eclipse Oxygen System is not a Division 2.2 gas and thus is not subject to the U.S. HMR.

*cell content?*

Lithium ion Batteries – 49 CFR 173.185

The Eclipse Oxygen System is powered by a lithium ion battery pack that has been tested pursuant to the UN Manual of Tests and Criteria. The pack is a unique design in that it contains two independent batteries. Each battery is electrically isolated and mechanically separated to prevent short circuits. The batteries are housed in a single, sturdily constructed plastic enclosure. The entire battery pack consists of 24, 2.2 ampere-hour lithium ion cells. Therefore, the pack contains an aggregate equivalent lithium content of 15.8 grams.

*how much*

Based on the requirements contained in 49 CFR 173.185(c), it is our opinion that the lithium ion battery pack is not subject to the HMR since the cells contain not more than 5 grams of equivalent lithium content, the battery pack contains not more than 25 grams of equivalent lithium content, the battery pack is of the type proven to be non-dangerous by testing in accordance with tests in the UN Manual of Tests and Criteria, and it will be packed in such a way to prevent short circuits when offered for transport or carried onboard passenger aircraft.

We also would like to point out that the U.S. HMR contain the following exception in 49 CFR 175.10(a)(27) (as amended by PHMSA's Interim Final Rule HM-224E) for passengers and crew members:

*“... consumer electronic and medical devices (watches, calculators, cameras, cellular phones, lap-top computers, camcorders, and hearing aids, etc.) containing lithium cells or batteries, and spare lithium batteries and cells for these devices, when carried by passengers or crew members in carry-on or checked baggage for personal use. In addition, each installed or spare battery must conform to the following: (i) The lithium content of the anode of each cell, when fully charged, is not more than 5 g; and (ii) The aggregate lithium content of the anodes of each battery, when fully charged, is not more than 25 g.”*

This provision is generally consistent with one found in the ICAO Technical Instructions that authorizes consumer electronic devices containing lithium ion batteries with up to 25 grams of equivalent lithium content to be carried onboard passenger aircraft.

\* \* \* \*

I trust the information contained herein is sufficient for PHMSA to provide a written determination that the Eclipse™ Oxygen System is not subject to the U.S. HMR. Should you need additional information or have any questions regarding our product, please do not hesitate to call me at the contact information below.

Respectfully,



Pamela J. Jackson  
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SeQual Technologies Inc.  
11436 Sorrento Valley Road  
San Diego, CA 92121

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cc: Robert Schneider, Vice President Business Development, SeQual Technologies Inc.  
Edward Radtke, Vice President Sales and Marketing, SeQual Technologies Inc.  
James Bixby, CEO and President, SeQual Technologies Inc.