



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

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

FEB 10 2011

Ms. Pamela J. Jackson
Senior Director, Government and Military
SeQual Technologies, Inc.
11436 Sorrento Valley Road
San Diego, CA 92121

Reference No. 10-0163

Dear Ms. Jackson:

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

You state that the SAROS™ Oxygen System is a device that separates oxygen from ambient air through a process called Pressure Swing Absorption (PSA). Your product was developed in cooperation with the US Army Medical Materiel Command to support the oxygen needs of patients on a battlefield. This device consists of a lightweight, portable oxygen concentrator with an integrated oxygen delivery valve for continuous flow or pulse delivery. The maximum pressure of the oxygen exerted within the SAROS™ 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 auxiliary DC power adapter for automotive applications. The battery pack consists of 16, 1.5 ampere-hour lithium ion cells, and the total equivalent lithium content of the battery pack is 7.20 grams or 86 Watt-hours. The lithium ion cells and battery pack have 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 SAROS™ 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 280 kPa absolute (40.6 psia) at 20 °C (68 °F); (2) the lithium ion battery used to operate the device is excepted from the HMR under § 172.102(c)(1), Special provision 188; (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).

Although the exception in § 175.10(a)(17) would apply to a passenger carrying a SAROS™ Oxygen System as described above, the approval of 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; copy enclosed) 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. 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 SAROS™ Oxygen System 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, appearing to read "T. Glenn Foster", with a long horizontal flourish extending to the right.

T. Glenn Foster
Chief, Regulatory Review and Reinvention Branch
Standards and Rulemaking Division

Stevens
§ 175.10 (a)(17)
Air
10-0163



SeQual Technologies Inc.
11436 Sorrento Valley Road
San Diego, CA 92121
Phone 858.202.3100
Fax 858.558.1915
www.sequal.com

July 22, 2010

Office of Hazardous Materials Standards
Pipeline and Hazardous Materials Safety Administration
U.S. Department of Transportation
1200 New Jersey Avenue, SE
Washington, D.C. 20590

Re: Classification of SeQual Technologies' Lithium ion Battery and SAROS™ Oxygen System

To Whom It May Concern:

I am writing to request written confirmation from the Pipeline and Hazardous Materials Safety Administration (PHMSA) that the lithium ion battery used in our new SAROS™ Oxygen System is not subject to the U.S. hazardous materials regulations (HMR) pursuant to Special Provision 188 and may be carried onboard passenger aircraft pursuant to 49 CFR § 175.10(a)(17).

Background

The SeQual SAROS Oxygen System is a device that separates oxygen from ambient air through a process called Pressure Swing Adsorption (PSA). The product was developed in cooperation with the US Army Medical Materiel Command to support the oxygen needs of the patients on the battlefield. The SAROS provides a solution to address both stationary and portable requirements for oxygen patients needing up to 3 LPM full flow operation and up to 96 ml flow in a pulse 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 Power Adapter or where standard AC line power is available. A 24 Volt DC Cable or the 12 Volt DC cable accessories allow power to be provided by a DC auxiliary power outlet, such as in a motor vehicle during transportation. Changeable and rechargeable battery packs are available to provide a range of ambulatory operational time.

The SAROS 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 SAROS 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 SAROS Oxygen System is not a Division 2.2 gas and thus is not subject to the U.S. HMR.

Lithium ion Batteries used in SAROS Oxygen System

The SAROS Oxygen System is powered by a lithium ion battery pack that consists of 16, 1.5 ampere-hour lithium ion cells. Therefore, the battery contains an aggregate equivalent lithium content of 7.20 grams (or 86 Watt-hours). The cells and battery have been tested pursuant to the requirements of the UN Manual of Tests and Criteria.

It is our opinion that the lithium ion battery is not subject to the HMR pursuant to Special Provision 188 because the cells contain not more than 1.5 grams of equivalent lithium content, the battery contains not more than 8 grams of equivalent lithium content, the cells and battery have been tested in accordance with the UN Manual of Tests and Criteria and the battery and SAROS Oxygen System will be packed pursuant to the requirements of Special Provision 188 when offered for transport. The battery also meets the exception found in 49 CFR 175.10(a) (17) for passengers and crew members. 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 100 Watt-hours to be carried onboard passenger aircraft.

* * * *

I trust the information contained herein is sufficient for PHMSA to provide a written determination that the SAROS™ Oxygen System and lithium ion battery used to power it are not subject to the U.S. HMR pursuant to Special Provision 188 and they meet the exception found in 49 CFR 175.10(a)(17) for passengers and crew members. 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
Senior Director, Government and Military
SeQual Technologies Inc.
11436 Sorrento Valley Road
San Diego, CA 92121
Phone: 858-202-3144
Cell: 760-805-9000
Email: pjackson@sequal.com