



U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

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

SEP 18 2013

Mr. Neal Maloy
Director – Quality and Regulatory Affairs
CHART-SeQual Technologies, Inc.
2200 Airport Industrial Drive, Suite 500
Ball Ground, GA 30107 USA

Ref. No.: 13-0177

Dear Mr. Maloy:

This responds to your August 26, 2013 letter requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to a portable oxygen concentrator (POC). Specifically, you inquire about obtaining Federal Aviation Administration (FAA) approval to allow a passenger to carry the POC aboard an aircraft.

According to your letter, the POC (trade name OXYWELL Oxygen System™) is a device that is for use by patients requiring high concentrations of oxygen on a supplemental basis. The maximum operating pressure of the OXYWELL Oxygen System™ is 23.7 pounds per square inch (psia). The OXYWELL Oxygen System™ is powered by multiple sources, including AC or DC power, and a rechargeable lithium-ion battery pack. For the OXYWELL Oxygen System™ powered by the rechargeable lithium-ion battery pack, the lithium-ion cells have an equivalent lithium content of 0.45 grams per cell and 7.20 grams of aggregate equivalent lithium content for the battery pack. The lithium-ion battery packs are types designed to meet the appropriate tests in the United Nations Manual of Tests and Criteria, and the battery packs are 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 OXYWELL Oxygen System™ is not subject to the HMR as a Division 2.2 non-flammable gas. The lithium-ion battery pack used to operate the device appears to conform to § 172.102(c)(1), Special Provision 188, for the transportation of small lithium cells and batteries and the POC contains no other hazardous materials. Therefore, the OXYWELL Oxygen System™ is not subject to any other requirements in the HMR.

Please note that notwithstanding the passenger exception in § 175.10(a)(18) of the HMR, Special Federal Aviation Regulation 106 (SFAR 106) “Rules for Use of Portable Oxygen Concentrator Systems on Board Aircraft” apply and are under the purview of the FAA, not the Pipeline and Hazardous Materials Safety Administration. This response letter satisfies

only one requirement in the FAA approval process before a POC may be operated onboard an aircraft. You may contact Ms. DK Deaderick in FAA's Flight Standards Service at (202) 267-7480 for questions regarding FAA's approval process.

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

Sincerely,



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



**CHART-SeQual
Technologies Inc.**

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August 26, 2013

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

Nickels
\$173.115
\$173.185
\$175.10
Applicability
13-0177

Re: Letter dated January 7, 2013; Ref. No. 12-0252

Dear Mr. Betts,

Per the referenced letter, the EQUINOX Oxygen System was granted an exemption from the U.S. hazardous materials regulations (HMR) in January 2013. The OXYWELL Oxygen System is based on the same concept as the EQUINOX Oxygen System and is a privately branded EQUINOX Oxygen System per the request of a customer in Japan. I am writing to request the petition for exemption from the U.S. hazardous materials regulations (HMR) to also include the OXYWELL Oxygen System.

I am requesting written confirmation from the Pipeline and Hazardous Materials Safety Administration (PHMSA) that Chart SeQual Technologies Inc. new portable oxygen concentrator (POC) device known as the "OXYWELL Oxygen System" is not subject to the U.S. hazardous materials regulations (HMR).

Background

The OXYWELL Oxygen System is a device that separates oxygen from ambient air through a process called Pressure Swing Adsorption (PSA). The OXYWELL provides a solution to address both stationary and portable requirements for oxygen patients needing up to 3 LPM full flow operation and up to 192 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 12-Volt DC cable allows 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 OXYWELL 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 OXYWELL Oxygen System packaging currently is 23.7 psia during normal operation at 20° C. This is substantially less than the 43.8 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 OXYWELL Oxygen System is not a Division 2.2 gas and thus is not subject to the U.S. HMR.

Lithium ion Batteries – 49 CFR 173.185

The OXYWELL Oxygen System is powered by a lithium ion battery pack designed to be compliant with the UN Manual of Tests and Criteria. The batteries are housed in a single, sturdily constructed plastic enclosure. The entire battery pack consists of 16, 1,500 milli-ampere-hour lithium ion cells. Therefore, the pack contains an aggregate equivalent lithium content of 7.20 grams.

Based on the requirements contained in 49 CFR 173.185, 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.

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I trust the information contained herein is sufficient for PHMSA to provide a written determination that the OXYWELL 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 contact me at the information below.

Our complete contact information is as follows:

Chart SeQual Technologies Inc.
2200 Airport Industrial Drive, Suite 500
Ball Ground, GA 30107 USA
Attn: Neal Maloy, Director - Quality and Regulatory Affairs
Phone: 770-721-7700
FAX: 770-721-7701
Email: Neal.Maloy@chart-ind.com

Best Regards,

A handwritten signature in cursive script that reads "Neal Maloy".

Neal Maloy
Director - Quality and Regulatory Affairs