



U.S. Department
of Transportation
**Research and
Special Programs
Administration**

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

MAR 24 2004

Mr. Robert S. Fary
Inogen Inc.
Vice President of Sales
120 Cremona Drive, Suite B
Goleta, CA 93117

Ref. No. 04-0053

Dear Mr. Fary:

This is in response to your letter dated March 10, 2004, regarding the applicability of the Department of Transportation's Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) to a device that your company calls the Inogen One portable oxygen concentrator.

The Inogen One portable oxygen concentrator is a device which separates oxygen from room air for delivery to patients who require supplemental oxygen therapy. It can be powered by multiple power sources, including a 12 cell rechargeable lithium ion battery, an AC power pack, and an automobile cigarette lighter adapter. The total equivalent lithium content of the battery pack is 7.92 grams and each cell of the battery pack has an equivalent lithium content of 0.66 grams. The process by which oxygen is separated is called pressure swing adsorption. This process utilizes a small air compressor, valves, and controlling electronics to pass air across a material called a molecular sieve. The material acts as a filter to nitrogen and passes the oxygen to the patient. The operating pressure of this device is approximately 39 psia. The oxygen concentrator contains no other hazardous material that is subject to the HMR.

Based on the information above, the Inogen One portable oxygen concentrator is not subject to the HMR because: (1) the pressure of the oxygen in the device never exceeds 40.6 psia at 68 °F; (2) the lithium ion battery used to operate the device is excepted from the HMR; and (3) the portable oxygen concentrator contains no other material subject to the HMR. Though the lithium ion battery is excepted from the HMR it must satisfy the requirements of § 173.21(c) which states that an electrical device is forbidden for transportation unless it 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).

I hope this satisfies your request.

Sincerely,

Edward T. Mazzullo
Director, Office of Hazardous
Materials Standards



040053

173.115

Gale
§173.115
Definitions
04-0053

John A. Gale
Transportation Regulations Specialist
U.S Department of Transportation
400 Seventh Street S.W.
Washington, DC 20590-0001

March 10, 2004

Dear John,

Once again, many thanks for allowing us to visit and present the Inogen One. I am excited about the changes that are coming that will result in increased access and convenience for oxygen users who travel.

I have attached the information you requested relative to the battery and the current standard. I am happy to say that we are within the guidelines stated in the regulation.

I respectfully request a letter from you that states that you have found the Inogen One to be safe and non-hazardous for use on commercial aircraft. Please e-mail the letter to me at rsfary@inogen.net.

Please do not hesitate to call me with any questions or issues that may arise.

Best Regards,

Robert S. Fary
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1. In response to questions regarding 49 CFR 173.115 (Definition of a Flammable Gas):

The regulations suggest that oxygen produced by the Inogen One oxygen concentrator should not be recognized as a "flammable gas" as the maximum pressure exerted within the product packaging is 39psia or less (depending on operating mode) at 20oC (and 1 bar ambient pressure), and is therefore less than the 40.6psia specified in 49CFR 173-115 paragraph (b)(1).

2. In response to questions regarding 49 CFR 173.185 (Lithium Batteries and Cells):

The Inogen One battery pack contains 12 cells of the 2.2Ah 18650 cell type. Each cell has an Equivalent Lithium Content of 0.66g*, for a total Equivalent Lithium Content of 7.92g.

Because (a) there is less than 1.5g of lithium per cell, (b) less than 8.0g total lithium, and (c) less than or equal to 12 cells per battery pack, an individual pack is not a Class 9 material. Each pack is strongly packaged and packed in a way to prevent short circuits.

Nonetheless, Inogen intends to and certifies that it will (1) label all of its batteries as containing lithium; (2) label any packaging for the battery to indicate that they contain lithium batteries, (3) qualify the battery through UN tests (T1-T8).

* Equivalent Lithium Content is measured as 0.3 times the rated capacity (ampere hours (Ah)) of the cell in Ampere-hours, with the results expressed in grams. The lithium-equivalent content of the battery equals the sum of the grams of lithium equivalent content contained in the component cells of the battery. (Example: an 18650 Li-ion cell with 1.8Ah of rated capacity would contain 0.54g of lithium (1.8 x 0.3) and 6 of these cells in a pack would equal 3.24g). *Source: "Overview of Lithium Transportation Regulations – as of May 2003), Panasonic Industrial Company."*

3. Additionally, 14 CFR 125.219 and 135.91 were mentioned. As both of these apply to rules governing use of devices on aircraft, and not the devices themselves, we feel they are not germane to this discussion.