U.S. Department
of Transportation

Pipeline and Hazardous Materials
Safety Administration

1200 New Jersey Ave., SE
Washington, DC 20590

AUG 6 2009

Mr. Matt Scribner
Inogen, Inc.
Bollay Drive
Goleta, CA 93117

Ref. No. 09-0155

Dear Mr. Scribner:

This responds to your July 6, 2009 letter requesting clarification of the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) to a portable oxygen concentrator. You request confirmation that the Inogen One G2 portable oxygen concentrator is not subject to the HMR.

Your company previously requested an interpretation in 2004 on the applicability of the HMR to the Inogen One portable oxygen concentrator. In our March 24, 2004 letter responding to your request, we stated that the device is not subject to the HMR provided the device is packaged in conformance with § 173.21(c).

According to your letter, your company has made design improvements to Inogen One, which will be marketed as Inogen One G2. The new version includes an optional 24-cell lithium ion battery pack to power the device consisting of two independent 12-cell battery packs. Each 12-cell battery pack operates independently in the same manner as the 12-cell battery pack that was used to power Inogen One. Specifically, the battery packs are electrically isolated and mechanically separated when enclosed in the device. Your letter also indicates that: (1) each lithium ion cell has an equivalent lithium content of 0.66 gram; (2) the total equivalent lithium content of each 12-cell battery pack is 7.92 grams; (3) the batteries are contained in the device and packaged in a manner to prevent sparks or the generation of a dangerous evolution of heat; (4) the pressure of the oxygen in the device is less than 40.6 psia at 20 °C (68 °F); (5) and no other hazardous material subject to the HMR is contained in the device.

You should be aware that since our March 24, 2004 letter, we have amended the HMR provisions applicable to lithium batteries, including the exceptions for small and medium lithium batteries. In a final rule published August 9, 2007, under Dockets HM-224C and HM-224E (72 FR 44930; copy enclosed), we relocated the exceptions for small lithium batteries in § 173.185(b) to Special Provision 188 in § 172.102(c)(1). In addition, we removed the exception for medium lithium batteries for transported by air, including the exception for batteries up to 25 grams aggregate lithium content when fully charged. Further, we added a new provision, beginning October 1, 2009, that small lithium cells and batteries must be of a type proven to meet the performance standards for applicable tests in the UN Manual of Tests and Criteria.

Based on the information provided, the oxygen in the Inogen One G2 portable oxygen concentrator is not subject to the HMR as a Division 2.2 non-flammable gas. Moreover, it is the opinion of this Office that the Inogen One G2 portable oxygen concentrator described in your letter and the lithium ion batteries contained in the device conform to the provisions of Special Provision 188. Therefore, provided the provisions in Special Provision 188 continue to be met, the Inogen One G2 portable oxygen concentrator is not subject to any other requirements in the HMR.

The approval of the Federal Aviation Administration (FAA) is required before portable oxygen concentrators may be used by passengers onboard 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 check with the airlines to ensure that the Inogen One G2 portable oxygen concentrator may be carried.

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

Sincerely,

Charles E. Betts
Chief, Standards Development
Office of Hazardous Materials Standards

Enclosure:

1. August 9, 2007 Final Rule: "Hazardous Materials; Transportation of Lithium Batteries"

2. July 12, 2005 Final Rule: "Use of Certain Portable Oxygen Concentrator Devices Onboard Aircraft"

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§173.185
§172.101
Applicability
09-0155

07/06/2009

U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Standards
1200 New Jersey Avenue, SE
Washington, DC 20590-0001

Dear Sir or Madam,

Enclosed is a submission to receive a confirmation from the Pipeline and Hazardous Materials Safety Administration that the new version of the Inogen One portable oxygen concentrator, which was the first concentrator to be approved by the FAA for use on commercial aircraft, continues to meet specifications allowing its use on aircraft.
We are aggressively attempting to make the FAA Regulatory Committee meeting scheduled for the 3rd week of July and need this confirmation in order to complete the package.
It is extremely important to Inogen, as this is our only product, that the updated version have the FAA approval upon its release in September.
Please contact me if you have any questions. I greatly appreciate your assistance in reviewing our changes.

Sincerely,

Matt Scribner
VP of Operations
Inogen, Inc.
Bollay Drive
Goleta, CA 93117

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Der Kinderen
§172.101
§173.185
Applicability
09-0155

07/06/2009

U.S. Department of Transportation
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Standards
1200 New Jersey Avenue, SE
Washington, DC 20590-0001

Dear Sir or Madam,

Inogen is requesting written confirmation from the Pipeline and Hazardous Materials Safety Administration (PHMSA) that the Inogen One G2 Portable Oxygen Concentrator is not subject to the U.S. Hazardous Materials Regulation (HMR) under HMR; 49 CFR Parts 100-180 after review of all appropriate information.

Inogen manufactures portable oxygen concentrators (POC) and has had the Inogen One available for commercial distribution since receiving 510(k) clearance from FDA on May 13, 2004. The Inogen One POC is currently allowed to be used onboard aircraft and was added to the SFAR No. 106 in the final published regulation on July 12, 2005. As part of that application, Mr. Mazzullo of the U.S. Department of Transportation sent a letter to Inogen stating that the Inogen One POC is not subject to the HMR.

Inogen Inc. has made design improvements to the Inogen One, which will be marketed as the Inogen One G2 Portable Oxygen Concentrator. The changes to the Inogen One are minor, but should help the user's mobility by providing increased battery life (2-4 hours), a smaller, lighter-weight device (less than 7 pounds), reduced noise, and an increase in the maximum rate of oxygen production (up to 900 ml/min). The Inogen One G2 has an optional 24-cell battery consisting of two independent 12-cell battery packs, rather than a single battery pack. Each pack operates independently with the exact same operating specifications as the single 12-cell battery pack in the previously-approved Inogen One. This additional accessory option avoids the patient's need to carry two separate batteries on the aircraft.

The Inogen One and the Inogen One G2 provide oxygen in the same manner, by separating oxygen from ambient air utilizing a molecular sieve and pressure swing adsorption methodology. The resultant concentrated oxygen is accumulated in an oxygen reservoir for delivery to the patient. This pressure in the Inogen One G2 is controlled in the same manner as the Inogen One to limit the pressure to less than 40.6 psia maximum. Both Inogen POCs deliver oxygen to the patient through the

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the ruling that the Inogen Portable Oxygen Concentrator is not subject to the Hazardous Material Regulation.

Inogen asks that the PHMSA confirm that the Inogen One G2 Portable Oxygen Concentrator is not subject to the U.S. Hazardous Materials Regulation under HMR 49 CFR Parts 100-180.

Please call or email if you have any questions. I can be reached at (805) 252-5089 or by email at mscribner@inogen.net

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Thank you for your attention.

Sincerely,

Matt Scribner
VP of Operations
Inogen, Inc.
Bollay Drive
Goleta, CA 93117

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