U.S. Department
of Transportation

1200 New Jersey Avenue SE
Washington, DC 20590

**Pipeline and Hazardous
Materials Safety
Administration**

OCT 1 2 2011

Mr. Matt Scribner
Vice President of Operations
Inogen, Inc.
326 Bollay Drive
Goleta, CA 93117

Ref. No. 11-0229

Dear Mr. Scribner:

This responds to your September 16, 2011 email 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 G3 portable oxygen concentrator (heretofore referred to as the G3) is not subject to the HMR.

Your company requested interpretations in 2004 and 2009 on the applicability of the HMR to previous generations of the G3. In our August 6, 2009 letter response, we stated that, provided the conditions in § 172.102, Special Provision 188 (SP 188) are met, the Inogen One G2 portable oxygen concentrator is not subject to further requirement under the HMR.

According to information provided with this request, your company has made modifications to Inogen One G2 resulting in the G3 design "without any functional changes that affect the overall safety of the device or its safe use on commercial aircraft." The most significant change to the G3 is a smaller battery. The G3 uses an 8-cell lithium ion battery pack and provides an optional extended life battery consisting of two 8-cell battery packs that are electrically isolated and mechanically separated when enclosed in the device. Specifically, you state: (1) each lithium ion cell has an equivalent lithium content of 0.87 gram; (2) the total equivalent lithium content of each 8-cell battery pack is 7 grams (~83.5 Wh); (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 limited to less than 43.8 psia at 20 °C (68 °F); and (5) no other hazardous material subject to the HMR is contained in the device.

Based on the information provided, the oxygen in the G3 is not subject to the HMR as a Division 2.2 non-flammable gas. Moreover, it is the opinion of this Office that the G3 device and the lithium ion batteries contained in the device appear to conform to SP 188 for the transportation of small lithium cells and batteries. Note that as one of the conditions of SP 188, the lithium ion batteries must be of a type proven to meet the requirements of testing in the UN Manual of Tests and Criteria. Thus, provided the conditions in SP 188 continue to be met, the G3 is not subject to any other requirements in the HMR.

As in our previous responses, we note that, 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 G3 may be carried aboard passenger aircraft.

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

Sincerely,

Ben Supko
Acting Chief, Standards Development Branch
Standards and Rulemaking Division

Der Kinderen
§ 172.102 SP 188
§ 173.185
Batteries / Applicability
11-0229

inogen

Sept 16, 2011

Standards and Rule Making PHH10
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Applicant:

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Re: Petition to Amend SFAR No. 106 on Portable Oxygen Concentrator Devices on Passenger Aircraft

Dear Sir or Madam:

Please accept this letter as petition to amend the Federal Aviation Administration's (FAA) Special Federal Aviation Regulation (SFAR) No. 106 under 14 CFR 121 that allows for the use of certain portable oxygen concentrator (POC) devices on board passenger aircraft. Inogen Corporation is specifically requesting that the FAA amend Section 2 and Section 3(a) of SFAR No. 106 by adding Inogen One G3 Portable Oxygen Concentrator, manufactured by Inogen, as one of the POC devices for use on passenger aircraft. The Inogen One and Inogen One G2 POCs have already been approved by the FAA and were added to the SFAR No. 106 in the final published regulation on July 12, 2005 and January 6, 2010 respectively.

Background

Inogen manufactures portable oxygen concentrators and has had the Inogen One available for commercial distribution since receiving the 510k clearance on May 13, 2004. The Inogen portable oxygen concentrators are lightweight, battery powered POCs intended for patients with respiratory disorders that require the use of supplemental oxygen. The devices are ideal for those patients who wish to have improved mobility and freedom to travel. The ability to travel on passenger aircraft is an important part of the quality of life that Inogen wishes to provide for its customers. All of Inogen's portable oxygen concentrator models are designed to be CSA certified to IEC-60601 for product safety and conform to all MDD requirements

Inogen has made design improvements to the Inogen One G2 which will be marketed as the Inogen One G3 Portable Oxygen Concentrator. These changes will improve the usability of the device for its customers. These changes are minor, but should help the user's mobility by providing a smaller, lighter-weight device (less than 5 pounds). As with the Inogen One and Inogen One G2, the G3 will fit under the seat and in the overhead bin of the smallest regional jets.

The Inogen One, Inogen One G2 and Inogen One G3 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 G3 is controlled in the same manner as the previous two models to limit the pressure to less than 40.6 psia. All Inogen POCs deliver oxygen to the patient through the pulse delivery method for maximum effectiveness and operational time. This means that a sensor in the Inogen One G3 detects the inhalation of the patient and delivers the oxygen in a bolus at that time. If no breath is detected because the patient takes the cannula off, no oxygen is delivered. Similarly, no oxygen is delivered during the exhalation which minimized the waste of oxygen. This feature of delivering oxygen on demand also minimizes accumulation of concentrated oxygen in the vicinity of the device.

The Inogen One G3 is an enhancement to the Inogen POC line without any functional changes that affect the overall safety of the device or its safe use on commercial aircraft. All of the components of the device relevant to the use on aircraft remain essentially the same. The most significant difference in the G3 is the smaller battery. Rather than having 12 cell battery packs like the Inogen One and Inogen One G2 batteries, the Inogen One G3 batteries are 8 cell packs and contain less lithium ion content per battery than either the G1 or G2 batteries which are 98Wh lithium ion batteries. Like the G2, the Inogen One G3 also has an optional extended life battery. This battery consists of two 8 cell

battery packs that are electronically isolated and mechanically separated. Each lithium ion cell in the G3 battery contains the equivalent lithium ion content of .870 grams. Each battery pack has a lithium ion content of 7 grams or 83.5 Wh and is designed and packaged to prevent sparks or the generation of a dangerous evolution of heat. Like the Inogen One G2 batteries, the G3 batteries are also individually CSA safety tested per IEC62133/UL1642.

FDA 510(k) Clearance Letter

The Inogen One Portable Oxygen Concentrator was determined by the FDA to be substantially equivalent to its legally marketed predicate devices on May 13, 2004. The device was granted clearance under K032818 under regulation number 21 CFR 868.5440, "Portable Oxygen Generator".

The Inogen One G3 Portable Oxygen Concentrator is an extension of the Inogen POC product line. It has minor modifications to improve its ability to meet the needs of the users. The Indications for Use for the device are identical to those of the Inogen One. The basic operating principle for the device, that it provide oxygen therapy through the pulse technology, remains unchanged with the Inogen One G3.

Inogen considers the Inogen One G3 POC to be a non-significant change from the Inogen One and Inogen One G2 design and materials. Under the FDA requirements for the Food, Drug and Cosmetic Act, Section 510(k) and the FDA Guidance Document K97-1 "Deciding when to Submit a 510(k) for a Change to an Existing Device", the Inogen One G3 device does not require a new 510(k) notification to the FDA. It does require documentation to Inogen's regulatory files and is then legally marketed under the existing cleared 510(k), K032818.

The Inogen One G3 will be available for sale under FDA clearance letter K032818. It is equivalent in design and use to the original Inogen One POC and the Inogen One G2, which have already been granted permission for use by FAA and passenger aircraft through amendments of SFAR 106. With the FDA clearance letter K032818 and the written documentation on file for the Inogen One G3, the Inogen One G3 will be marketed to persons requiring supplemental oxygen and who desire greater mobility.

PHMSA Letter of Interpretation

In 2004 and in 2009, Inogen submitted requests to the US Department of Transportation and to the Pipeline and Hazardous Material Safety Agency asking for written interpretation that the Inogen One POC and Inogen One G2 POC were not subject to the U.S. Hazardous Materials Regulation (HMR) as

referenced in 49 CFR Parts 171-180. On March 2004 and August 2009, Inogen received confirmation that the Inogen One POC and Inogen One G2 POC were not subject to the HMR.
Because the operating specifications for the Inogen One G3 do not exceed any of the specifications of the Inogen One or Inogen One G2 and the batteries used by the Inogen One G3 contain less equivalent lithium ion content than the Inogen One or Inogen One G2, batteries Inogen is confident that the G3 is not subject to the Hazardous Material Regulation. Attached is a copy of the 3/24/04 letter from Edward Mazzullo, DOT, stating that the Inogen One is not subject to the Hazardous Material Regulations and also a copy of the August 6, 2009 letter from Charles E. Betts, Chief, Standards Development, Office of Hazardous Materials Standards confirming that the Inogen One G2 is also not subject to the HMR as a division 2.2 non-flammable gas and that the batteries conform to the provisions of Special Provision 188.

Summary

Inogen believes that the information contained in this petition provides sufficient information for the PHMSA to determine that the Inogen One G3 Portable Oxygen Concentrator, by design, does not meet the criteria for hazardous material and the batteries of the Inogen One G3 conform to the provisions of Special Provision 188. The availability of this concentrator will benefit those patients who require supplemental oxygen on a regular basis and who want to be able to travel on aircraft. The Inogen line extension to its portable oxygen concentrator has made the device lighter weight, smaller and easier for patients to use. The ability to carry the unit onboard aircraft will enhance the quality of life for the users of the device.

The Inogen One G3 is a non-significant change in function and operation when compare to the earlier generations of the Inogen One POCs that have already been approved for use on aircraft by the FAA. We therefore respectfully request that the section 2 and section 3 of the SFAR No. 106 be amended by adding the Inogen One G3 as an approved POC for use onboard passenger aircraft.

Should you need any additional information or have any questions regarding this product, please feel free to contact me by phone or email.

Respectfully submitted.

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