



U.S. Department
of Transportation

Pipeline and Hazardous Materials
Safety Administration

1200 New Jersey Ave., SE
Washington, DC 20590

JAN 08 2009

Mr. William R. Wilkinson
Vice President of Engineering
International Biophysics Corporation (IBC)
2100 East St. Elmo Rd.
Austin, TX 78744

Ref. No. 08-0266

Dear Mr. Wilkinson:

This is in response to your October 13, 2008 letter regarding the applicability of the Hazardous Materials Regulations (HMR; 49 CFR Parts 100-180) to a device your company calls the LifeChoice Portable Oxygen Concentrator (POC).

You state in your letter and a subsequent conversation with a member of my staff that the LifeChoice POC is a lightweight device that separates nitrogen from room air through the pressure swing absorption (PSA) process and stores the resultant concentrated oxygen gas for delivery to patients requiring supplemental oxygen. This device delivers the oxygen to the patient through the pulse dose delivery method. The maximum internally attainable pressure during the PSA cycle of the device is 22 psig (36.7 psia) over an operating temperature range of 5 °C to 40 °C (41 °F to 104 °F), with a maximum oxygen accumulator quantity of 45 mil per minute for operation in the pulse mode. The device can be powered by multiple power sources, including an internally captive, rechargeable lithium ion battery pack, AC to DC power adaptor, by an external DC to DC power adapter, or an external accessory lithium ion battery pack. The internally captive lithium ion battery consists of 8 rechargeable 2.2 amp-hour lithium ion cells with 0.3 grams of lithium content each, or a total of 5.2 grams of total equivalent lithium content (0.3 x 2.2 Ah x 8 cells), and no other hazardous materials. The external accessory battery module consists of two battery packs, each containing a total of 5.2 grams of total equivalent lithium content, or a total of 10.4 grams of total equivalent lithium content. The lithium ion battery pack has 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 LifeChoice POC is not currently subject to the HMR because it meets the following criteria:

1. The pressure of the oxygen in the device does not exceed 280 kPa (40.6 psia) at 20 °C (68 °F);
2. The lithium ion batteries used to operate the device are excepted in the HMR;

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).

You should also note Federal Aviation Administration (FAA) approval is required before these electronic devices are used by passengers on board aircraft. The FAA published a final rule in the Federal Register regarding these devices on July 12, 2005 (70 FR 40156). 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 the air carrier ultimately determines what may or may not be carried on its aircraft. We suggest that you check with the air carrier to ensure that the LifeChoice portable oxygen concentrator may be carried.

I hope this satisfies your inquiry. If we can be of further assistance, please contact us.

Sincerely,

A handwritten signature in black ink, appearing to read "Hattie L. Mitchell", with a long horizontal flourish extending to the right.

Hattie L. Mitchell
Chief, Regulatory Review and Reinvention
Office of Hazardous Materials Standards



I n t e r n a t i o n a l B i o p h y s i c s C o r p o r a t i o n

October 13, 2008

Foster
§173.115 (b)(1)
Definitions
08-0266

Mr. Edward Mazzullo
Director
Pipeline and Hazardous Materials Safety Administration
Office of Hazardous Materials Standards
1200 New Jersey Avenue, SE East Building, 2nd Floor
Washington, DC 20590

Re: International Biophysics Corporation, LifeCho₂ice Portable Oxygen Concentrator

Dear Mr. Mazzullo,

International Biophysics Corporation (IBC) is requesting written confirmation from the Pipeline and Hazardous Materials Safety Administration that the LifeCho₂ice Portable Oxygen Concentrator (POC) is not subject to the U.S. hazardous materials regulation under HMR; 49 CFR Parts 100-180 after review of all appropriate information.

P 512.326.3244
F 512.326.3299

www.IBCbio.com

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Austin, TX 78744

LifeCho₂ice POC is a light weight device that separates nitrogen from room air through the pressure swing absorption (PSA) process and stores the resultant concentrated oxygen gas for delivery to patients who need supplemental oxygen therapy. LifeCho₂ice delivers the oxygen to the patient through the pulse dose delivery method for maximum effectiveness and power efficiency. This means that a pulse of oxygen of the correct quantity is delivered through the nasal cannula only when an inhalation is detected. With this method, accumulations of excess oxygen in the surrounding environment are minimized.

The maximum internally attainable pressure during the PSA cycle of the LifeCho₂ice POC is 22 PSIG (36.7 PSIA) over an operating temperature range of 5 degrees Celsius and 40 degrees Celsius. As this maximum operating pressure is below 40.6 PSIA at 20 degrees Celsius for a division 2.2 gas in CFR 173.115(b)(1), IBC believes the LifeCho₂ice POC is not subject to the U.S. HMR regulation for oxygen gas.

The LifeCho₂ice POC can be powered by an internally captive, rechargeable lithium ion battery pack that is not removable or replaceable by the user of the device, by an external AC to DC power adapter, by an external DC to DC power adapter, or an external accessory lithium ion battery pack. This allows for maximum flexibility and operational time with multiple power sources. Recharging is only available with the use of the AC-DC or DC-DC power adapters.

Since 1992,
International
Biophysics
Corporation has
manufactured
medical devices
and surgical
components.

IBC is proudly
certified as ISO 9001
and ISO 13485

The internally captive lithium ion battery consists of 8 rechargeable 2.2 amp-hour lithium ion cells. Therefore, the total equivalent lithium content is $0.3 \times 2.2 \text{ Ah} \times 8 \text{ cells} = 5.2$ grams of equivalent lithium content for this internal battery.

The internally captive lithium battery is not user accessible and not replaceable by a patient/user. It is securely captured in the product. The internally captive mechanism of the LifeCho₂ice POC also prevents any user from generating sparks or short-circuiting as it is not externally accessible. The battery pack terminals are not exposed to any outside contact by virtue of being totally integrated into the product.

The external accessory battery module for extended operating time is a self contained separate battery accessory for the LifeCho₂ice POC. The external battery module contains two battery packs. Each battery pack contains 8 rechargeable lithium ion cells of 2.2 amp-hour per cell. Therefore, the total equivalent lithium content per battery pack is $0.3 \times 2.2 \text{ Ah} \times 8 \text{ cells} = 5.2$ grams of equivalent lithium content per battery pack. Therefore, the external battery module contains a total of 10.4 grams which is less than 25 grams of equivalent lithium content in its two battery packs. The external accessory battery module is not user accessible and the cells contained within the module are not replaceable by the patient/user. This captive mounting mechanism of the external battery module also prevents any user from generating sparks or short-circuiting of the lithium ion battery pack. The battery pack terminals are not exposed to any outside contact as they are connected to an intervening power switching and charging circuit board that interfaces to the LifeCho₂ice POC. The external battery module connection cable contains a connector that prevents accidental shorting or generation of sparks during handling and storage.

IBC believes that based on the requirements of 49 CFR 173.185(c)(2), both the internally captive lithium ion batteries and the lithium ion external battery module are exempt from the HMR requirements. The individual cells do not contain more than 1.5 grams of lithium equivalent content and each battery does not contain more than 8 grams of lithium equivalent content. The external battery module contains less than 25 grams of lithium equivalent content in aggregate in its two batteries. In addition, both the internally captive and external accessory battery module are packed securely within their respective product cases and are protected from short-circuiting and spark generation.

IBC believes that all the other materials used in the device are not subject to the U.S. hazardous materials regulation under HMR 49 CFR Parts 100-180.

To Summarize:

1. The pressure of the oxygen in the LifeCho₂ice POC does not exceed 40.6 PSIA at 20 degrees Celsius;
2. The cells contain not more than 1.5 grams of lithium equivalent content;
3. The lithium ion battery packs contain an aggregate equivalent lithium content of not more than 8 grams;

4. The device contains no other materials subject to the HMR; and
5. The batteries are fully contained in the equipment and packaged in a manner to preclude sparks or the generation of a dangerous quantity of heat.

Based on all of the above, IBC believes that the LifeCho₂ice POC and the accessory external battery module meet special provision 188.

In addition, IBC understands that the FAA approval is required before the LifeCho₂ice POC may be used by passengers on board aircraft. We have already submitted an application to Mr. David Catey of the FAA and he has informed us that the remaining requirement is the letter from your office that states that LifeCho₂ice POC meets Special Provision 188, and not otherwise subject to the HMR.

Thank you for your time and attention on this matter. If any further information is required, please contact me at (512) 326-3244 Extension 110.

Sincerely,
International Biophysics Corporation



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CC: Len Hickey
Operations and Regulatory Affairs Manager