



U.S. Department
of Transportation
**Research and
Special Programs
Administration**
MAY 11 2004

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

Mr. Jeff Jerome
CEO - Nene Labs
5115 Gage
Boise, Idaho 83706

Ref. No.: 03-0303

Dear Mr. Jerome:

This responds to your letter regarding the classification and shipment of a portable "OX-GEN Flexible O2 Generation System, Model 6-OX-03," containing a water solution of approximately 7.5 % hydrogen peroxide by weight and manganese oxide, as a catalyst, in accordance with the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). The OX-GEN Flexible O2 Generation System is intended to produce oxygen for emergency uses. The OX-GEN Flexible O2 Generation System delivers over 8 liters per minute of 99% pure oxygen for a minimum of 15 minutes by means of a chemical reaction. The portable oxygen generator system is composed of two parts, described as follows:

The reaction vessel consists of a plastic bag, with two chambers separated by a weak seal. The weak seal is welded plastic which breaks at about 10 pounds of pressure achieved by squeezing the bag toward the weak seal. The bag contains an outlet of chemically non-reactive tygon tubing attached to the hydrophobic filter. The bag (reaction vessel) reached a maximum average pressure of 4.2 lbs/psi. The hydrophobic filter is not reactive with hydrogen peroxide or oxygen, and allows O₂ (oxygen) gas to pass, but no liquid, and leads to a standard oxygen mask.

The chemicals in the reaction vessel consists of a water solution of approximately 7.5 % H₂O₂ (hydrogen peroxide) by weight in one chamber, and a small amount of MnO₂ (manganese dioxide) in the smaller chamber. The MnO₂ is a catalyst in the reaction, and liberates one of the oxygen molecules from the H₂O₂, yielding H₂O (water) and O₂ (oxygen). Since the reaction is exothermic, heat is generated. At the end of the reaction, the temperature of the reactants is approximately 68°C - 72°C. The maximum temperature of the O₂ at the end of the reaction is 32°C - 34°C. After the reaction is complete (less than 20 minutes), the entire apparatus is thrown away. The final by-products at the end of the reaction are water and manganese dioxide. All components in this system are designed for single use only.



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Based on the information you provided, it is this Office's opinion that a water solution of approximately 7.5 % hydrogen peroxide by weight does not meet the definition in § 173.127 as a Division 5.1 (Oxidizer). The manganese oxide (principal reactant) may be an oxidizer if data or experience indicates that it meets the definition in § 173.127 as a Division 5.1 (Oxidizer). As defined in § 171.8 of the HMR, an oxygen generator (chemical) means a device containing chemicals that upon activation releases oxygen as a product of chemical reaction. A device that meets the definition in § 171.8 for an "Oxygen generator (chemical)," must be described on a shipping paper as "Oxygen generator, chemical, 5.1, UN 3356, PG II," and all other applicable rules of the HMR would apply.

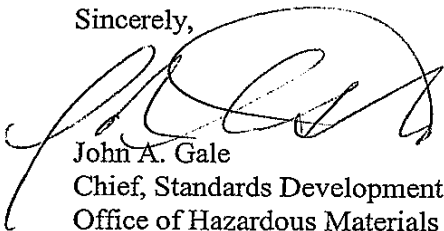
In § 172.102, Special Provision 60 specifies that a chemical oxygen generator that is shipped with its means of initiation attached must incorporate at least two positive means of preventing unintentional actuation of the generator, and be classed and approved by the Associate Administrator for Hazardous Materials Safety. Procedures for filing for an approval request are found in Subpart H of Part 107 of the HMR.

Each person who offers a chemical oxygen generator for transportation must: (1) ensure that it is offered in conformance with the conditions of the approval; (2) maintain a copy of the approval at each facility where the chemical oxygen generator is packaged; and (3) mark the approval number on the outside of the package. For example, since the product is designed to be flexibly operable with very light pressure breaking the membrane between the activating catalyst and the reactant hydrogen peroxide solution, preventing unintentional activation may necessitate that the soft flexible pouch be enclosed in a rigid container for transportation.

Transportation of a chemical oxygen generator is forbidden on passenger-carrying aircraft. A spent, chemical oxygen generator is forbidden on passenger-carrying and cargo-only aircraft. Special Provision A51 specifies that when transported by cargo-only aircraft, an oxygen generator must conform to the provisions of Special Provision 60 and be contained in a packaging prepared and originally offered for transportation by the approval holder.

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

Sincerely,



John A. Gale
Chief, Standards Development
Office of Hazardous Materials Standards

NENE LABS

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for the betterment of the Family

Engrum
\$ 173.22
Shipper's Responsibility
03-0303

November 12, 2003

Edward Mazzullo
USDOT/RSPA, DHM-10
400 7th Street South West
Washington, DC 20590-0001

Mr. Mazzullo,

Our sales representative (Jeff Morris) talked with you two weeks ago in regards to getting a hazardous materials qualification from you on a product we are developing for OX-GEN.

Here is a draft of our 510 (k) for the FDA. Hopefully it is detailed enough for you to determine if our product will be considered Hazardous Material, or will be exempt.

510 (k) Formulations

Please let me know what we need to do next to get the classification.

Thank you for your time,

Product of
Soak and Heal™
Ibuprofen Analgesic
Bath Tablets with Aloe



-Jeff Jerome

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