U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, D.C. 20590

SEP 17 2008

Mr. John M. Lansdown
Director of Research
OxySure Systems, Inc.
10880 John W. Elliott Rd., Suite 600
Frisco, TX 75034

Ref. No. 08-0095

Dear Mr. Lansdown:

This is in response to your letter and subsequent telephone conversations with members of my staff regarding the Hazardous Materials Regulations (HMR; 49 CFR 171-180) applicable to chemical oxygen generators. We apologize for the delay in responding and hope it has not caused any inconvenience.

In your letter, you state that your company manufactures a portable chemical oxygen generator, the OxySure Model 615, which delivers medically pure oxygen for use in cardiovascular, respiratory, and general medical emergencies. You state the initiation of oxygen generation is via a mechanical mechanism which releases a plunger. The plunger breaks the internal seals, bringing the oxygen-producing powder and catalyst together in a "slurry." You state that the housing and most of the internal parts are injection-molded plastic, and oxygen is delivered via a latex-free tubing and mask assembly. You ask whether an approval is required for the transportation of your product.

The answer is yes. As currently required in Special Provision 60, 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. In addition, the HMR regulations pertaining to a chemical oxygen generator are applicable to your product, including, after October 1, 2008, compliance with § 173.168, which includes impact resistance, packaging, and marking requirements.

I hope this satisfies your inquiry.

Sincerely,

Edward T. Mazzullo

Edward T. Mazzullo
Director
Office of Hazardous Materials Standards

OxySure® Systems, Inc.

Foster
§173.168
Portable Oxygen Generato
08-0095

April 15, 2008

Attention: Mr. Edward Mazzullo, Director
Office of Hazardous Materials Standards, PHH-10
U.S. DOT/PHMSA
Via DHL and Facsimile: (202) 366-7435

Dear Mr. Mazzullo,

RE: EMERGENCY RELIEF FROM DOT HAZMAT REGULATIONS FOR FDA APPROVED PORTABLE OXYGEN GENERATOR

We are seeking an emergency interpretation by the Office of Hazardous Materials Standards regarding our consumer medical product. We were directed to the Standards Office by Ms. Harpreet Singh from the Office of Hazardous Materials Special Permits and Approvals.

We have developed a product that delivers medically pure (USP) oxygen for use in cardiovascular, respiratory and general medical emergencies. The device is safe and easy to use, such that bystanders or laypersons can administer medical oxygen in an emergency while waiting for first responders to arrive on the scene. The device, called the OxySure® Model 615 was deemed safe enough to have received FDA approval (510(K), Class II) for Over-the-Counter sale to consumers.

We are seeking emergency relief from the hazardous materials shipping regulations as they relate to traditional chemical oxygen generators (49CFR §172.200, §172.300, §172.400, §173.22, §173.56, §173.168,). These regulations are created to address the hazards associated with the chemical oxygen generators traditionally used in commercial aircraft. I have attached a copy of a letter addressed to the Permits and Approvals office describing the OxySure® Model 615 Emergency Oxygen system and contrasting it to traditional chemical oxygen generators. I have also attached the MSDS for Model 615.

Please do not hesitate to contact me if you need any additional information.

Sincerely,

John M. Lansdown, Ph.D.
Director of Research
OxySure® Systems, Inc.

Enclosures: Letter to PHMSA, Permits and Approvals - 10 Apr 2008
MSDS, OxySure® Model 615

10880 John W. Elliott Road, Suite 600, Frisco, TX 75034 USA
Frisco, Texas Office: (+1) 888-7OXYSURE Fax: (+1) 972-294-6501
Virginia Office: (+1) 703-687-1616 Fax: (+1) 703-580-7496

OxySure® Systems, Inc.

April 10, 2008

US. DOT/PHMSA
Office of Hazardous Materials Special Permits and Approvals, PHH-30
Via DHL, Facsimile: (202) 366-3308 and Email: phmsaapprovals@dot.gov

Dear Sir/Madam,

Thank you for your call yesterday, and we are very pleased to learn that a revision to the regulations regarding chemical oxygen generators may be imminent. We have a mission-critical and time-critical need to get direction in this regard.

Our technology is vastly different to the old chlorate technology (for which the current regulations is written) used in commercial aircraft, and was developed precisely to eliminate the hazards associated with it and other, traditional oxygen delivery systems. In fact, our first product, the OxySure® Model 615 was deemed safe enough by the Food & Drug Administration to be approved for Over-the-Counter (OTC) sale to consumers as a Class II medical device (Approval number K052396).

Background and Model 615
OxySure® Systems, Inc. spent the last 6 years developing a next-generation technology for the delivery of medical oxygen through a safe chemical process. In the process, we have developed numerous patents on the technology.

Our first product based on this technology is a Portable Emergency Oxygen Generator called Model 615. Model 615 is indicated by the FDA to be used for emergency oxygen, usually in cardiac, respiratory or other general medical emergencies. It is also well suited for applications in civil emergencies and other homeland security applications. The product is designed to prevent harm or possibly death in emergency situations by providing lifesaving oxygen. It is designed to be safe and simple to use, such that any bystander or layperson can administer medical oxygen while waiting for the first responders to arrive on the scene.

The OxySure® Model 615 produces a minimum of 6 liters per minute for a minimum of 15 minutes of medically pure (USP) oxygen. This is the FDA standard for emergency oxygen. Model 615 was developed specifically to fill the need for a safe, easy to use portable oxygen source that did not have the risks associated with compressed gas cylinders, liquid oxygen, or the type of emergency oxygen source used in commercial aircraft. Like a fire extinguisher, Model 615 can be safely pre-positioned in homes, buildings and other public and private settings to provide immediate medical grade oxygen in an emergency. Model 615 has already been used in published cases where lives were saved through its use, including the case of an

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elementary school child in South Carolina. In January 2008 the OxySure® Model 615 was named to the 2008 list of the World's Best Technologies.

Technology
The OxySure® Model 615 contains 3 components stored in separate hermetically sealed compartments: an inert, dry powder, which is the oxygen source, a catalyst, and a liquid. Unlike a compressed gas source, Model 615 does not contain a regulator, but rather produces oxygen at very close to atmospheric pressure. The initiation of oxygen generation is via a mechanical mechanism which releases a plastic plunger that breaks the internal seals bringing the oxygen producing powder and catalyst together in a slurry. The housing and most of the internal parts are injection-molded plastic. Lifesaving oxygen is delivered to the person in need via a latex-free tubing and mask assembly.

The chemical components are stored inside a self-contained, disposable cartridge. The operating temperatures are much lower than traditional chemical oxygen generators and thus the device is not capable of igniting a fire. The device operates at very close to atmospheric pressure so it does not present the types of hazards represented by compressed gas cylinders or liquid oxygen. The device is not an explosion hazard. The chemicals are non toxic and environmentally safe.

Not a Temperature Hazard
The OxySure® process results in oxygen generation at a temperature much lower than traditional chemical oxygen generators used in commercial aircraft as PSUs. The outside surface of the unit only rises a few degrees F and the temperature of the oxygen produced increases typically only 5 to 10 degrees F above ambient temperature. Typically, the breathing temperature experienced by the user is less than 90° F. The temperatures within the slurry of the reaction are typically in the 150°F range, well below the temperature needed to initiate combustion. Of course, the user is well insulated from the reaction core, such that the touch temperature of the cartridge is far less than that of a Starbucks coffee cup.

Not an Explosion Hazard
The OxySure® Model 615 is not an explosion hazard. The oxygen generating process is initiated with the turn of a knob, causing the oxygen containing powder, catalyst and liquid to be instantly combined inside the cartridge. Prior to the reaction, the powders are dry and inert. Post-reaction, the residue of the reaction consists of a harmless slurry. Therefore, Model 615 is not an explosion hazard, either prior to the reaction or after.

Furthermore, we have completed several tests with Model 615 in the presence of a fire. We found that when the cartridges are placed in a fire, the plastic components simply melt. Non-activated cartridges placed in a fire melted, releasing the liquid in some cases. Even activated cartridges placed in a fire did not markedly enhance the activity of the fire, if at all. In summary, Model 615 is not an explosion hazard, not under normal circumstances nor under the aggravated circumstances of a fire.

Not a Toxicity Hazard
The oxygen producing powder used in Model 615 does not represent a toxicity hazard in the same way that, for example, the barium peroxide (used presently in commercial aircraft) represents a toxicity hazard. From our MSDS you will see that accidental contact with the

powder produces no more than a mild skin irritation which can be alleviated by rinsing with water.

Not an Environmental Hazard
Upon accidental release due to the integrity of the cartridge being broken, for example, during shipment, the oxygen producing powder does not represent an environmental hazard. Once the cartridge is spent, it contains a slurry which is safe to dispose of in regular household trash.

Not a Pressure Hazard
OxySure® Model 615 is a non-pressurized oxygen source. Oxygen gas is not stored in the cartridge but rather produced upon activation. Under normal operating conditions, the pressure within the system is well within 1 atm. Pressure relief valves at the top of each chamber prevent the cartridge from developing an internal pressure higher than 1 atm. in case of an accidental activation, i.e., activation without the mask tubing attached.

This is a summary of the significant safety technologies incorporated into the OxySure® Model 615 Emergency Oxygen system. We would be delighted to provide all third party validations, test data and any other material you may require. In addition, there may be more helpful information on our website located www.oxysure.com, including an instructional video showing how the product works.

If you have any questions or require any additional information please do not hesitate to contact me or Julian Ross, President and CEO of OxySure® Systems, Inc. directly.

Sincerely,

John M. Lansdown, Ph.D.
Director of Research
OxySure® Systems, Inc.

Material Data Safety Sheet

1 Product and Company Identification

Article Name:	OxySure® Portable Emergency Oxygen Generator, Model 615	
Application of the product:	Supplemental Oxygen for Emergency Use	
Manufacturer/Supplier	OxySure® Systems, Inc 10880 John W. Elliott Drive, Suite 600 Frisco, TX 75034 Tel : 888-7-OXYSURE Fax : 972-294-6501 www.oxysure.com	
Emergency Information	Call CHEMTREC International	800-424-9300 (24 hrs) 703-527-3887

2 Composition/Information on Components

Molded Plastic Parts:	Primarily Polycarbonate and PC/ABS	
	Polycarbonate	44%
	PC/ABS	28%
	Starex ABS	12%
	Steel, Stainless Steel, Brass	4%
	Celcon, Polypropylene, Silicone, Nylon	<2% EA
	Celenex, Polyethylene, PVC,	<1% EA
User Mask and Tubing:	Latex Free Polyethylene	
Oxygen Producing Ingredients:	OxySure® Powder	60%
	Accelerant	40%
	OxySure® Catalyst	≤1%

3 Hazards Identification

As supplied, and under normal use, this product consists of a cartridge and/or a housing for the cartridge. The major component of the outer housing is PC/ABS. The major component of the cartridge is polycarbonate.

Gases and fumes evolved during the thermal decomposition of this material may irritate the eyes, skin or respiratory tract.

Hazardous Materials Identification System (HMIS) Rating (scale 0 – 4):

HEALTH: 0
FLAMMABILITY: 1
REACTIVITY: 0
SPECIAL HAZARD(S):

As supplied, and under normal use, the oxygen-producing ingredients are self-contained in the cartridge, and user will not make any contact with the cartridge ingredients. However, if the cartridge contents spill out as a result of accidental breakage of the cartridge:

Avoid contact with skin and eyes and inhalation of any dust.

Hazardous Materials Identification System (HMIS) Rating (scale 0 – 4):
HEALTH: 2
FLAMMABILITY: 0
REACTIVITY: 1

National Fire Protection Association (NFPA) Rating (scale 0 – 4)
HEALTH: 2
FLAMMABILITY: 0
REACTIVITY: 1

4 First Aid Measures

General Information

As supplied, and under normal use, this product consists of a cartridge and/or a housing for the cartridge. The major component of the outer housing is PC/ABS. The major component of the cartridge is polycarbonate. The oxygen-producing ingredients are self-contained in the cartridge. If the cartridge contents spill out as a result of accidental breakage of the cartridge:

After inhalation of dust:	Allow the victim to rest in a well ventilated area. Seek immediate medical attention.
After skin contact:	Wash immediately with plenty of water for 15 minutes. Remove contaminated clothing and shoes. Gently and thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. Cover the irritated skin with an emollient. If irritation persists, seek medical attention.
After eye contact:	Flush eyes with plenty of water for 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Check for and remove any contact lenses. Do not use an eye ointment. Seek medical attention.
After Swallowing:	Wash out mouth with water provided person is conscious. Seek medical attention.

5 Fire fighting measures

Suitable extinguishing agents:	Water, Carbon dioxide (CO_2), dry chemical, powder, or appropriate foam.
Protective equipment:	Wear self-contained breathing apparatus and protective clothing to prevent against potentially toxic and irritating fumes and to avoid contact with skin and eyes.
Unusual Fire/Explosion Hazards:	Oxygen-generating device - the presence of oxygen can increase the rate and intensity of flame. Toxic and irritating gases/fumes may be given off during burning or thermal decomposition. If the cartridge contents spill out as a result of accidental breakage of the cartridge, contact may exacerbate an existing fire hazard.

6 Accidental release measures

As supplied, and under normal use, the oxygen-producing ingredients are contained within the plastic housing. If the contents spill out as a result of an accidental breakage of the plastic housing:

Avoid contact with skin and eyes and inhalation of any dust. Avoid contact of dry powder with combustible material. Use appropriate tools to put the spilled solid in a convenient waste disposal container. Avoid raising dust. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements.

7 Handling and Storage

Handling:

Information for safe handling:	Handle in accordance with good industrial hygiene and safety practices.
Information about protection against explosions and fires:	No special measures required.

Storage:

Requirements to be met by store rooms and receptacles:	Store at room temperature; 70°F to 86°F (21°C to 30°C). Store in cool, dry place. Do not attempt to open cartridge.
Information about storage in one common storage facility:	Not required.

Transportation:

Conditions: Temperature Limits During Transportation:	Low limit: 40°F (4°C) High limit: 149°F (65°C) If product is exposed to temperatures outside the transportation exposure limits (lower than 40°F or higher than 149°F), the cartridge must be replaced.

8 Exposure controls and personal protection

As supplied, and under normal use, this product consists of a cartridge and/or a housing for the cartridge. The major component of the outer housing is PC/ABS. The major component of the cartridge is polycarbonate.

Additional information about design of technical systems:	N/A
Components with limit values that require monitoring at the workplace:	The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

If the cartridge contents spill out as a result of accidental breakage of the cartridge:

Personal protection equipment:

General protective and hygienic measures:	Avoid contact with eyes and skin. Use compatible chemical-resistant gloves, chemical safety goggles. Remove and wash contaminated clothing. Discard contaminated shoes. Avoid inhalation of dust, use government-approved respiratory filter device. Do not ingest.

9 Physical and chemical properties

	Molded Polycarbonate parts
Form	Solid
Color	various
Boiling point/range:	N/A
Flash point:	N/A
Vapor Pressure:	N/A
Density:	1.19-1.23 g/mL
Specific Gravity:	
Solubility in Water:	Insoluble
Autoignition Temperature:	N/A
	Molded PC/ABS parts
Form	Solid containing solid and liquid components
Color	Off white, gray, black
pH	N/A
Boiling point/range:	N/A
Flash point (PC/ABS):	608°F (320°C)
Lower Explosion Limit:	Not Established
Upper Explosion Limit:	Not Established
Vapor Pressure:	N/A
Density:	N/A
Specific Gravity:	N/A
Solubility in Water:	Insoluble
Autoignition Temperature:	900 °F (482°C)
Decomposition Temperature:	531°F (277°C)
Softening Point:	392°F (200°C)
Bulk Density:	N/A
	Oxygen producing Ingredients: OxySure® Powder
Form	Coarse Powder
Appearance	Free flowing white granular powder
Color	White
pH	10.0 ± 1
BP/BP Range	N/A
MP/MP Range	N/A
Freezing Point	N/A
Vapor Pressure	N/A
Vapor Density	N/A
Saturated Vapor Conc.	N/A
Bulk Density	N/A
Odor Threshold	N/A
Volatile%	N/A

VOC Content	N/A
Water Content	N/A
Solvent Content	N/A
Evaporation Rate	N/A
Viscosity	N/A
Surface Tension	N/A
Partition Coefficient	N/A
Decomposition Temp.	N/A
Flash Point	N/A
Explosion Limits	N/A
Flammability	N/A
Autoignition Temp	N/A
Refractive Index	N/A
Optical Rotation	N/A
Miscellaneous Data	N/A
Solubility	N/A

N/A= Not Available

10 Stability and reactivity

As supplied, and under normal use, this product consists of a cartridge and/or a housing for the cartridge. The major component of the outer housing is PC/ABS. The major component of the cartridge is polycarbonate.

Hazardous Reactions:	Hazardous polymerization does not occur
Stability:	Stable
Materials to avoid:	None known
Conditions to avoid:	None known

Hazardous decomposition products

By Fire and Thermal Decomposition:	Carbon Dioxide (CO_2); water; styrene; acrylonitrile; hydrogen cyanide; carbon monoxide, hydrocarbons

Dangerous Reactions:

Dangerous products of decomposition:	No dangerous decomposition products known.

As supplied, and under normal use, the oxygen-producing ingredients are self-contained in the cartridge. If the cartridge contents spill out as a result of accidental breakage of the cartridge:

Materials to avoid:	Strong reducing agents, strong acids, organic materials, salts of metals, flammable substances.
Conditions to avoid:	Extreme Heat or Flame

11 Toxicological information

As supplied, and under normal use, this product consists of a cartridge and/or a housing for the cartridge. The major component of the outer housing is PC/ABS. The major component of the cartridge is polycarbonate.

Skin Irritation:	Rabbit, Draize, Non-irritating
Eye Irritation:	Rabbit, Slightly irritating
Sensitization:	Dermal: Non-sensitizer (Guinea pig, Buehler Test)
Repeated Dose Toxicity:	28 days, Oral: NOAEL: 1.862 mg/kg (rat, Male/Female, daily)
Mutagenicity	Genetic Toxicity in Vitro: Ames: Negative results were reported in various in vitro studies

As supplied, and under normal use, the oxygen-producing ingredients are self-contained in the cartridge. If the cartridge contents spill out as a result of accidental breakage of the cartridge:

RCRA, it is the responsibility of the product user to determine at the time of disposal whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24).

16 Other Information

Department issuing MSDS: OxySure® Systems, Inc.

Contact: Director of Research

Disclaimer: To our knowledge, the information contained herein is accurate as of the date of this document However, OxySure Systems, Inc., does not warrant, expressly or impliedly, or accept any liability in connection with this information or its use This information is for use by technically skilled persons at their own discretion and risk and does not relate to the use of this product in combination with any other substance or any other process. This is not a license of any patent, trademark or other intellectual property. The user alone must finally determine suitability of any information or material for any contemplated use, the manner of use and whether any intellectual property rights are infringed.

Routes of Entry:	Eye contact. Inhalation. Ingestion
Acute Toxicity (oral):	LD50 1.9g/kg ~ 3g/kg
Irritation:	Eye. skin, mucous membrane

12 Ecological Information

As supplied, and under normal use, this product consists of a cartridge and/or a housing for the cartridge. The major component of the outer housing is PC/ABS. The major component of the cartridge is polycarbonate. .

Biodegradation:	Not readily biodegradable
Bioaccumulation:	Does not bioaccumulate
Acute and Prolonged Toxicity to Fish:	LC50: 18 mg/L (Common Carp (Cyprinus caprio, 96 hrs))

As supplied, and under normal use, the oxygen-producing ingredients are self-contained in the cartridge. If the cartridge contents spill out as a result of accidental breakage of the cartridge:

General notes:

There is a limited amount of ecological data available on the oxygen-generating ingredients of this product.

13 Disposal considerations

Product:

Recommendations:	Spent disposable cartridge can be placed in household trash. Do not attempt to open spent cartridge. If/where applicable, do not dispose of a cartridge that is unactivated - return unactivated cartridges to OxySure®.

14 Transport Information

Consumer Product. Contains consumer quantities of oxygen-producing ingredients. No special labeling requirements.

15 Regulatory Information

Product is intended to supply medical oxygen for emergency use. FDA approval number K052396.

As supplied, and under normal use, this product consists of a cartridge and/or a housing for the cartridge. The major component of the outer housing is PC/ABS. The major component of the cartridge is polycarbonate.

OSHA Hazcom Standard Rating:	Non-Hazardous
US Toxic Substances Control Act:	Listed on the TSCA Inventory

US EPA CERCLA Hazardous Substances (40 CFR 302; Components): None

SARA Section 311/312 Hazard Categories: Non-hazardous under Section 311/312

US EPA Emergency Planning and Community Right-To Know Act (EPCRA) SARA Title III Section 302 Extremely Hazardous Substance (40 SCR 355, Appendix A; Components): None

US EPA Emergency Planning and Community Right-To Know Act (EPCRA_ SARA Title III Section 313 Toxic Chemicals (40 CFR 372.65) – Supplier Notification Required (Components): None

US EPA Resource Conservation and Recovery Act (RCRA) Composite List of Hazardous Wastes and Appendix VIII Hazardous Constituents (40 CFR 261):

If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under