

FDA and NIOSH Public Health Advisory

Explosions and Fires in Aluminum Oxygen Regulators

(You are encouraged to copy and distribute this Advisory)

February 1999

**To: Fire Departments
Safety Directors
Biomedical Engineers
Nursing Homes
Emergency Transportation Services**

**Rescue Squads
State EMS Systems
Hospital Administrators
Home Health Care Agencies
Risk Managers**

This notice is to advise you of hazards with oxygen regulators made of aluminum and to provide recommendations regarding these devices.

THE PROBLEM

Over the past 5 years, the FDA has received 16 reports of aluminum regulators used with oxygen cylinders burning or exploding. These incidents caused severe burns to 11 health care workers and patients. Many of the incidents occurred during emergency medical use or during routine equipment checkout. FDA and The National Institute for Occupational Safety and Health (NIOSH) believe that the aluminum in these regulators was a major factor in both the ignition and severity of the fires, although there are likely other contributing factors. Most of the reports received by FDA were for the Model L270 series of aluminum regulators manufactured by Life Support Products Inc. and Allied Healthcare Products Inc. (Earlier models were known as "270" regulators.)

Allied Healthcare Products currently has 60% of the market share of oxygen regulators for emergency use. The manufacturer has plans to cease the distribution of all regulators containing aluminum and solely manufacture brass regulators. In an effort to avoid potential product shortages, Allied is instituting an interim measure wherein they will replace internal high-pressure aluminum components with brass components in all models manufactured.

Because aluminum is lighter in weight than steel, it is also used in oxygen cylinders. FDA and NIOSH believe that aluminum cylinders can be used safely with brass regulators, but that the combination of both oxygen regulators and cylinders made from aluminum poses an increased fire hazard. Contamination of the oxygen supply with particulate matter can also increase the risk of fire.

BACKGROUND

Most oxygen regulators are made of brass or aluminum. Aluminum and its alloys were more likely to ignite than brass. In standard tests, aluminum can burn vigorously at pressures as low as 25 pounds per square inch (psi), while brass does not burn at pressures below 10,000 psi. Although there are rare instances of fires in brass oxygen regulators, they have a long history of safe use and are believed to be safer than aluminum oxygen regulators for use with high pressure compressed oxygen. FDA has no reports of fire or explosion with aluminum in oxygen regulators used in low pressure systems (e.g., piped distribution to wall mounted supply taps at <50 psi).

RECOMMENDATIONS

FDA is pursuing plans to work with manufacturers to improve the safety of oxygen regulators and restrict the use of aluminum exposed to high-pressure oxygen in regulators. In the meantime, FDA and NIOSH advise that the following precautions be taken to avoid explosions and fires from oxygen regulators containing aluminum:

- If you are presently using high pressure oxygen regulators which contain any aluminum exposed to high-pressure oxygen, replace them with regulators made of brass. Consult the manufacturer if you don't know what material is used in your regulators.
- If non-aluminum oxygen regulators are not available, it is recommended that you follow the precautions as described in the addendum to this advisory to minimize the risk of fires until brass replacement regulators become available.

REPORTING ADVERSE EVENTS TO FDA

The Safe Medical Devices Act of 1990 requires hospitals and other user facilities to report deaths, serious illnesses, and injuries associated with the use of medical devices. Questions about mandatory reporting can be answered by the Division of Surveillance System, Reporting Systems Branch by phone on (301) 594-2735 or FAX, (301) 827-0038 or write to FDA, CDRH, MDR User Reporting, P.O. Box 3002, Rockville, MD 20847-3002. Written reports will go into FDA's MDR data base. Submit voluntary reports directly to the FDA's voluntary reporting program, MedWatch; by telephone at (800) FDA-1088, by FAX at (800) FDA-0178, or by mail to: MedWatch, Food and Drug Administration (HFA-2), 5600 Fishers Lane, Rockville, MD 20857-9787.