



## **The Ethylene Oxide Sterilization Association, Inc.**

### **Ethylene Oxide -- Is It Being Banned?**

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The Ethylene Oxide Sterilization Association, Inc. (EOSA) is a non-profit organization whose members include medical device manufacturers, sterilization consultants, laboratories, contract sterilizers, and equipment manufacturers with a common interest in promoting the safe use of ethylene oxide (EO). EOSA works to educate industry, regulators, and the public on the uses and benefits of EO. EOSA also works to improve safety standards, foster industry communication, and provide a forum for many subjects related to EO sterilization.

Some blends of EO and hydrochlorofluorocarbons (HCFC) used for medical device sterilization are being banned per current Montreal Protocol requirements. This has resulted in some confusion in the industry regarding the future of EO and its role in medical device sterilization. The purpose of this document is to provide some current facts regarding EO.

#### **What Are the Facts?**

- The production of chlorofluorocarbons (CFC) was banned in the U.S. as of January 1, 1996. In compliance with the Montreal Protocol, certain HCFCs are scheduled to be phased-out by January 1, 2015, including the HCFCs that are used in EO/HCFC blends for sterilization.
- Although the phase-out of HCFCs will cause the production and use of EO/HCFC blends to be discontinued in the near future, this phase-out is unrelated to the usage of EO itself as a sterilant.
- Today, the medical device manufacturing industry uses EO to sterilize more than 56 percent of all medical devices (Source: 3M Health Care and ARC Specialty Products).
- More than 7,000 100 percent EO sterilizers are in use today, in every state in the continental U.S. and in more than 70 countries (Source: 3M Health Care).
- EO is the most common chemical sterilant. The market for EO sterilization is strong and continues to grow at 1.5-3 percent per year (Sources: ARC Specialty Products and Honeywell International).
- There are over 4 billion pounds of EO produced in the U.S. annually, the majority of which is used to make antifreeze, fibers, detergents, surfactants, and numerous other vital consumer and industrial products. With so many applications and such a large volume generated annually, the supply of EO for sterilization purposes should be sustainable for the indefinite future (Source: ARC Specialty Products).