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Comparison of health care-based sterilization technologies: Safety, efficacy, and economics

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Figure 6. Comparative toxicities

Sterilant	TLV (OSHA)	IDLH (NIOSH)	RQ (EPA)	Health (NFPA)	Tumorigen mutagen
ETO	1 ppm	800 ppm	10 lb	2	Yes
Hydrogen peroxide	1 ppm	75 ppm	1 lb	3	Yes
Hydrogen peroxide/ Peracetic acid mix	1 ppm	75 ppm	1 lb	3	Yes

Figure 6. Comparative toxicity: consisting of the threshold limit value (TLV), the concentration thought to be an "immediate danger to life and health" (IDLH), EPA Reportable Quantity (RQ), and NFPA 704 Health Hazard assignment for 100 percent ETO, Hydrogen Peroxide, and Peracetic Acid/ Hydrogen Peroxide mixture (extrapolated).

would have a TLV of about 1 ppm. It is appropriate to note that peracetic acid decomposes to acetic acid, for which the TLV is 10 ppm, and H_2O_2.

Another significant toxicological exposure limit, used by the NIOSH to indicate the potential for a substance to present an "immediate danger to life and health" (IDLH), has a value of 800 ppm for ETO but only 75 ppm for H_2O_2 and 50 ppm for acetic acid. That means that NIOSH and others believe that it will require a significantly lower exposure and/or dose of H_2O_2 and/or acetic acid to present an immediate danger to the health of an employee, as compared to the dose of ETO.

The EPA has named ETO, H_2O_2 and peracetic acid to its list of Extremely Hazardous Substances. Acetic acid also appears in the Toxic Substances Control Act (TSCA) inventory list. However, ETO spills have an EPA reportable quantity (RQ) of 10 lbs, while H_2O_2, and peracetic acid have reportable quantities of only 1 lb. The RQ is the quantity of an Extremely Hazardous Substance, spilled or released, that triggers mandatory notification of the local fire department, the Local Emergency Planning Committee (LEPC), the State Emergency Response Commission (SERC), and the National Response Center (NRC). Notification is required within 30 minutes of the spill or release. The RQ is a relative measure of the individual hazardous materials spill consequences.

NFPA, under the previously discussed "704" system, has assigned a health risk of "2" to ETO, a "3" to H_2O_2, and a "3" to peracetic acid, thus attributing greater health risk to the latter chemical sterilants. All three materials are mutagenic and tumorigenic, according to a host of published toxicological and industrial hygiene literature. Both ETO and H_2O_2 are capable of producing cancer in experimental animals, with ACGIH classifying hydrogen peroxide as an animal carcinogen.[18]

Thus, as compared to ETO, the IDLH and RQ limits are 10 times less for H_2O_2 and for the peracetic acid/H_2O_2 mixture, the NFPA Health Risk rating is greater, and the TLVs are equal. Does this mean that H_2O_2 and its mixtures with peracetic acid are more dangerous and/or more toxic than ETO? That may be so, but at least a rough equality is established among the three materials in terms of toxicity and their hazardous nature. In addition, ETO and hydrogen peroxide both generate concerns about carcinogenicity and reproductive effects.

Regarding the liquid phase of these sterilants, ETO, due to its very high vapor pressure and volatility, evaporates extremely rapidly and produces frost bite on exposed skin. On the other hand, H_2O_2, due to its very low vapor pressure, tends to remain liquid and forms droplets and aerosols. Hydrogen peroxide presents a very severe corrosive hazard to skin and other tissue (including the eye and lungs), producing blistering, ulceration, and discoloration upon contact.

We need to understand fully that there is no escape from the significant problems associated with working with extremely hazardous materials by simply abandoning nonflammable ETO sterilizing technology. The toxicity issues and related risks are every bit as important with all forms of current sterilizing technology, including the H_2O_2 plasma process and the peracetic acid/H_2O_2 plasma process. Eliminating or at least minimizing exposure of personnel to the sterilant is an essential and mandatory concern for all practitioners of sterilization, regardless of the technology utilized.

Recent independent studies[19,20] of health care facility sterilizer operating personnel utilizing H_2O_2 plasma revealed surprising results. H_2O_2 vapor had been detected upon the opening of the sterilizer door at the conclusion of the cycle in the operator's Breathing Zone (BZ). The results from a number of measurements demonstrate that the short-term, localized, H_2O_2 concentration

Figure 7. Operator removing processed packages from a hydrogen peroxide plasma sterilizer.

exceeded 3 ppm after the plasma sterilizer door was opened. Some of the personnel performing the sterilizing operations reported episodes of eye and mucous membrane irritation. Packages removed from the sterilizer after one hour continued to emit residual H_2O_2 gas at short-term or instantaneous concentrations of up to 2.5 ppm, for up to 1.3 hours following their removal from the sterilizer.

In addition, Easterling,[21] among others,[22] observed and measured similar concentrations of H_2O_2 and peracetic acid during operation of the mixed component plasma system.

Monitoring data obtained by MacNeal and Glaser[22] suggest that there is similarity in the timing and location of peak peroxide levels with both the H_2O_2 plasma and the peracetic acid/H_2O_2 plasma systems. Observation and measurement suggests that the peak peroxide concentrations may be significantly higher with the peracetic acid/H_2O_2 plasma system, despite that system's series of "air washes." This would seem to suggest that a separate aeration cycle might be required to remove residual peroxides from certain items processed by either of the plasma units. Certain types of packaging and packaging materials appear to retain greater amounts of the residual chemicals for extended periods of time—many hours to days—upon removal from the sterilizer.

In addition to measurable concentrations of H_2O_2 vapor in the operator's BZ, we have identified at least one documented case of dermal exposure to liquid hydrogen peroxide by an operator of a H_2O_2 plasma system. The operator was splashed on the face by a droplet of H_2O_2, which rapidly produced severe blistering and caused a pronounced discoloration of the skin. At the time the injury took place, the operator was removing items from the sterilizer.

The toxicology literature[23] notes that sensitive individuals can experience upper respiratory tract irritation from hydrogen peroxide exposure at sub-ppm (less than 1 ppm) concentrations. It has been reported that residual H_2O_2 on disinfected endoscopes has been, on occasion, responsible for a form of chemically-induced colitis. Thus it is interesting to note that H_2O_2 is not "non-toxic," apparently does not decompose immediately and completely to "non-toxic products" by the end of the cycle, and can remain as a toxic residue on or in some processed packages for an extended period of time. Much the same can be said for the peracetic acid/H_2O_2 plasma process.

Given the similar toxicities of H_2O_2 and peracetic acid, as compared to ETO, one cannot help but wonder how long it will be before H_2O_2 and peracetic acid are each subjected to workplace regulatory health and safety controls similar to those of ETO established by OSHA and state regulatory agencies.

There already exist applicable OSHA regulations that require written hazard communication plans, emergency spill cleanup procedures, possible medical monitoring, and, of course, training of and for employees who work with hazardous chemicals, as well as documentation and record keeping requirements. Even in the absence of such regulation, we now know enough to warrant virtually identical practices for worker protection while using any of these potent chemicals. No one would consider knowingly exposing workers to ETO. With the newly documented operator exposure data, how then can exposures to H_2O_2 and/or peracetic acid, which are equally insidious, be permitted?

Considerations for sterility assurance and biological indicators

In an ongoing series of reports by Peter Mecke *et al* published in the German journals *Zentral Sterilisation* and *Hygiene-Medizin*, the German Society for Hospital Hygiene made a number of significant criticisms relating to the biological and chemical indicators used with the H_2O_2 plasma technology.[24,25]

Specifically, the reports include the following comments:

- The microorganism utilized, *B. subtilis*, is considerably less resistant to the H_2O_2 plasma sterilization process than is *B.*