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Comparison on Safety Concern Among Gamma-Ray, Autoclave and Ethylene Oxide Gas Sterilizations of Thermosetting Polyurethane

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Sterilization of polyure thane (PU) produces 4,4'-methylenedianiline (MDA), a known carcinogen, and various others including hydrophilic and hydrophobic compounds. The relationships between PU components and MDA formation by several methods of sterilization were confirmed using thermosetting PU. Specimens of PU fabricated from different combination of isocyanates and polyols were obtained from dialyzers (detailed omitted in this editorial). The molecular weight of the particular poluol was found to influence the production of MDA by sterilization. Sterilization also produced many unidentified compounds. MDA production was not always associated with the production of the other compounds. Compared with gamma-ray irradiation sterilization, ethylene oxide gas (EOG) sterilization, and autoclave sterilization, gamma-ray irradiation sterilization produced most MDA (Figure 1). This phenomenon was significant for PU produced from smaller molecular weight polyols. The combination of autoclave sterilization and a PU produced from a larger molecular weight polyols is recommended to minimize the production of potentially toxic compounds. Of the techniques studied, EOG sterilization produced the least amounts of MDA and the other compounds, but the residue of EOG is itself problematic. Sterilization produced more MDA from PUs fabricated with smaller-molecularweight polyols than from PUs fabricated from larger-molecular-weight polyols.

Seventeen peaks including that for MDA, were observed in HPLC



Figure 1: HPLC chromatograms of methanol extracts in protocol I-I, I-II and I-III

I-I is control, I-II is gamma-ray irradiation at 27 kGy and I-III is autoclave sterilization at 121.1 $^{\circ}\mathrm{C}$ for 30 min. I-I, I-II, and I-III are prepared using castor oil as polyol and MDI

I-I, I-II, and I-III are prepared using castor oil as polyol and MDI (methylenediisocyanate) as isocyanate.



chromatograms of the sterilized PU samples (Figure 2). Comparing gamma-ray sterilization with autoclave sterilization, autoclave sterilization tended to produce greater amounts of hydrophilic compounds.

Various compounds of unknown composition were produced by the sterilization of PU. However, the amounts of the unknown compounds produced varied depending on combinations of the sterilization methods and the components of PU; therefore, the hazardous effect of sterilization can be diminished by selecting an appropriate combination of sterilization method and PU components. As shown in the chromatogram, the combination of autoclave sterilization and a PU fabricated from a larger-molecular-weight polyol was observed to attain the least toxic compound production. Autoclave sterilization is desirable, although the number of polymers that can tolerate moist heat is limited. Among autoclave, gamma-ray, and EOG sterilization, EOG sterilization produced the smallest amounts of potentially toxic compounds, but there remains the problem of the carcinogenic EOG residue.

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The biological safety as well as the chemical structures of the compounds other than MDA eluted after sterilization of PU must be identified to determine their carcinogenic potentials.

The risk posed by the amounts of MDA extracted was not significant, but the biological safety of the other compounds remains to be determined.