STERILIZER TECHNOLOGY

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The Effect of Sterilization Methods on Various Polymeric Packaging Materials

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The demand for plastics for packaging has grown rapidly over the past decade and has surpassed $3.5 billion per year. Plastics, as a general rule, do not corrode or deteriorate (under normal environmental conditions), which makes them ideally suited for a variety of packaging applications. For certain applications, such as medical devices, pharmaceuticals, veterinary products, and biologics, the plastic must be able to withstand some form of sterilization. The common methods of material sterilization are: dry heat, ethylene oxide gas, gamma radiation, and electron beam radiation.

Many thermoplastics cannot be sterilized by heat because of low softening points, usually below 100 degrees Celsius. Radiation is an effective procedure for polymers that are sensitive to heat , moisture, or ethylene oxide. Radiation in a plastic causes an excited state that releases free radicals, which, in turn, cause crosslinking or cut the molecular chains (chain scission). In many cases, both crosslinking and chain scission occur, but, frequently, one mechanism predominates in a specific polymer. Crosslinking may initially increase tensile strength, but it lowers impact strength and causes the plastic to become more brittle. Chain scission reduces strength and stiffness, lowers fatigue and the ability to elongate, and weakens adhesive bonds. Many polymers will discolor upon radiation, becoming yellow and sometimes cloudy or even opaque. Discoloration is affected by the presence of oxygen and may develop several weeks or even months after the plastic has been irradiated.

Polymers containing aromatic molecules, such as polystyrene or polyimide, tend to resist the effects of radiation better than aliphatic polymers. The use of fillers and reinforcement agents help to improve radiation stability. Moreover, various additives can help minimize the effects of radiation by absorbing energy, thereby quenching the excited state and preventing breakdown. Another concept is that additives will accept the free radicals before they can damage the molecular chains. Aromatic additives and antioxidants assist a material to resist aging as well as radiation. Some of the effective additives include sulfhydryl compounds, ascorbate, dimethyl sulfoxide, proteins and carbohydrates. Tin-based compounds are used in polymer formulations to inhibit discoloring.

Steam autoclaving, which typically operates at approximately 270 degrees Fahrenheit, should be used where dry heat might cause distortion or degradation of a polymer component.

Ethylene oxide gas (EtO) is widely used for sterilization and is harmless to most plastics. Sometimes ethylene oxide gas causes a surface glazing condition in some polymers.

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In sterilization employing electron beam (E-beam) radiation, high energy electrons are added externally to the atom, in contrast to gamma radiation rays which interact with an atom's electrons, raising their energy level to an excited state. The E-beam radiation electrons are accelerated in a single direction, whereas gamma rays travel through the product in all directions. The dose rates for E-beam are roughly 100 times greater than they are for gamma radiation; therefore, the E-beam process is faster for it only takes a few minutes for E-beam to sterilize a product, compared to several hours for gamma. The shorter exposure period for E-beam leads to possibly less material damage. E-beam increases product temperature ten to twenty degrees Celsius, and if the heat generated will harm the plastic, the energy of the E-beam can be decreased. Unlike gamma decay, which occurs continuously, E-beam can be turned on and off as desired and is much easier to control the exact dosage than with ethylene oxide gas.

Types of radiation-induced changes vary with each specific polymer. Crystalline polymers become hard and brittle, but only at very high doses. Degradative changes may accompany crosslinking. Polypropylene nylon and pressure-sensitive adhesives are subject to oxidative degradation. Polyvinyl chloride (PVC) and polyvinylidine chloride (PVDC) evolve hydrochloric acid and polytetrafluoroethylene (PTFE) evolves hydrogen fluoride. PVC discolors at 2.5 Mrad and Teflon disintegrates to a powder. There has been some success in stabilizing polypropylene to a radiation process of 2.5 Mrad. Tygon, a PVC copolymer, is stable to 2.5-3 Mrad. Polyethylene (low and high density) and polystyrene present no problems, for polystyrene is one of the most stable of the synthetic materials. Phenolics, epoxy resins, and polyester resins are also stable to high doses. Silicone rubber is more stable than other types of rubber.

Acrylics soften with autoclaving, and radiation may cause chemical degradation. EtO gas is unsatisfactory for molded articles because of poor gas penetration. Radiation of cellulose acetate may reduce strength, while ethylene oxide gas is satisfactory. Heat and gas may be used safely on fluorocarbons, while radiation is unsuitable for PTFE. Fluorinated ethylene-propylene copolymers are more radiation resistant. Polypropylene may be autoclaved and gas sterilized, although newer formulations are more resistant to radiation. EtO is satisfactory for polyvinyl chloride, although discoloring and crosslinking occurs with radiation, unless properly stabilized.

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A great deal of information is available from government reports, industrial literature and scientific publications concerning the various stabilization methods and their effects on the physical/chemical properties of specific polymers. The requirement of complete knowledge of a formulation, and the thorough testing of polymeric materials under various sterilization methods, is absolutley mandatory for product package success.

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