

Effects of Irradiation Sterilisation on Medical Grade Poly (ether-block-amide)

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Abstract. Poly (ether block amide) (PEBA) is a family of copolymers which consists of polyamide hard segments and polyether soft segments in the polymer chains. These are thermoplastic elastomers (TPE) which are sold under Arkema's trade name PEBAX[®]. They are mainly used in the medical device industry as they offer valuable properties such as elasticity and thermal stability at body temperatures. Its applications range from catheter bodies to angioplasty balloons. For medical device usage, it is of vital importance that the material properties are not deteriorated by sterilisation using ionising irradiation techniques. During radiation exposure, polymers usually undergo simultaneous scission and crosslinking but one generally predominates over the other. The objective of this study was to quantify the effects of electron beam (combined 10/12MeV unit, 30KW) and gamma ray processing on PEBAX material through a diverse array of characterisation techniques. Mechanical testing revealed that the tensile strength and the percentage elongation at break of PEBAX reduced dramatically from 25kGy to 200kGy. This was perhaps related to branching and chain scission occurring simultaneously. Branching can limit the packing of polymer chains and lead to the formation of free volume in the material, therefore causing a reduction in the tensile strength and elongation at break. Gamma irradiation resulted in further modifications to the mechanical properties of PEBAX in contrast to electron beam irradiation. Both processes lead to an extreme decrease in the melt flow index which was perhaps as a result of branching / crosslinking. Dynamic frequencies sweeps revealed that the storage modulus increased in the low frequency regime for the gamma irradiated samples while the electron beam irradiated samples remained unchanged. It was observed by SEM that the surface morphology of the non-irradiated (0kGy) sample contained a homogeneous pattern which was much smoother than that of the electron beam irradiated (200kGy) sample. XRD demonstrated slight alteration to the peak intensities signifying a slight change in the polymer matrix. Overall, chain scission and branching were the key modification processes involved which occurred simultaneously. However, it was evident from the results obtained that chain branching/crosslinking was the predominant phenomena particularly at high irradiation dose rates. In addition, this study proved that the gamma ray process was more detrimental on the PEBAX material in contrast to the electron beam process.