Stabilization Packages for Medical Plastics

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Medical devices continue to become smaller as innovation aims to minimize invasiveness to the body. In the medical plastics industry, many extruded and injection molded parts have extremely thin walls. Oxidative degradation on the surface of such parts influences bulk mechanical properties to a greater extent than in larger parts due to the phenomena of diffusion limited oxidation. Briefly, a thin layer of oxidized polymer on the surface hinders the transport of oxygen within the part, acting as a protective barrier against further oxidation. However, the total wall thicknesses of some parts such as catheters can be smaller than this oxidized barrier layer, making them more susceptible to mechanical failure. Furthermore, the life cycle of medical plastics often comprises several melt processes, annealing, sterilization, and some length of time between these processes and packaged on the shelf before getting used, all of which contribute to oxidation and increase the risk of failure during use.

Compounding Solutions' R&D staff is working to optimize stabilization packages for commonly used medical plastics to minimize oxidation and extend their lifetime. In an ongoing study, several stabilization packages were compounded, extruded into tubing with 0.078" inner diameter, 0.004" wall thickness, and aged in various environments.

Initial results show drastic improvement in physical property retention of poly(ether-block-amide) (PEBA) using a synergistic blend of stabilizers. The elongation at break and molecular weight of PEBA with 55shD hardness aged at room temperature under a UV lamp are shown in Figure 1. The predominant degradation mechanisms under these aging conditions are photooxidation and thermal oxidation. Proprietary synergistic stabilization package Stabilize Rx 101 compounded at 0.5 wt.% total loading is compared to compounding traditionally used stabilizers Irganox® 1010 and Tinuvin® 622 and tubing extruded directly from PEBA without the additional melting cycle introduced by compounding. As seen in these data, PEBA greatly benefits from additional stabilizers and higher stabilizer concentrations offer more protection. At an equivalent total loading of 0.5 wt.%, Stabilize Rx 101 outperforms traditionally used stabilizers. The addition of Stabilize Rx 101 at 0.5 wt.% does not create a chalky surface and does not alter color or transparency. Stabilize Rx 101 does not have cytotoxic potential according to ISO 10993-5 test results.

Using optimized stabilization packages such as Stabilize Rx 101 delays the effects of oxidative degradation and helps to extend shelf life, but polymers eventually become brittle and discolored as free radicals cleave chains, induce crosslinking, and produce chromophores. Oxidation can only be fully prevented by eliminating the presence of oxygen during processing and storage, which is not realistic. Minimizing the amount time spent in the melt state, reducing exposure to UV, gamma, or other radiation, and maintaining lower temperatures are all still recommended guidelines during all manufacturing and storage procedures.

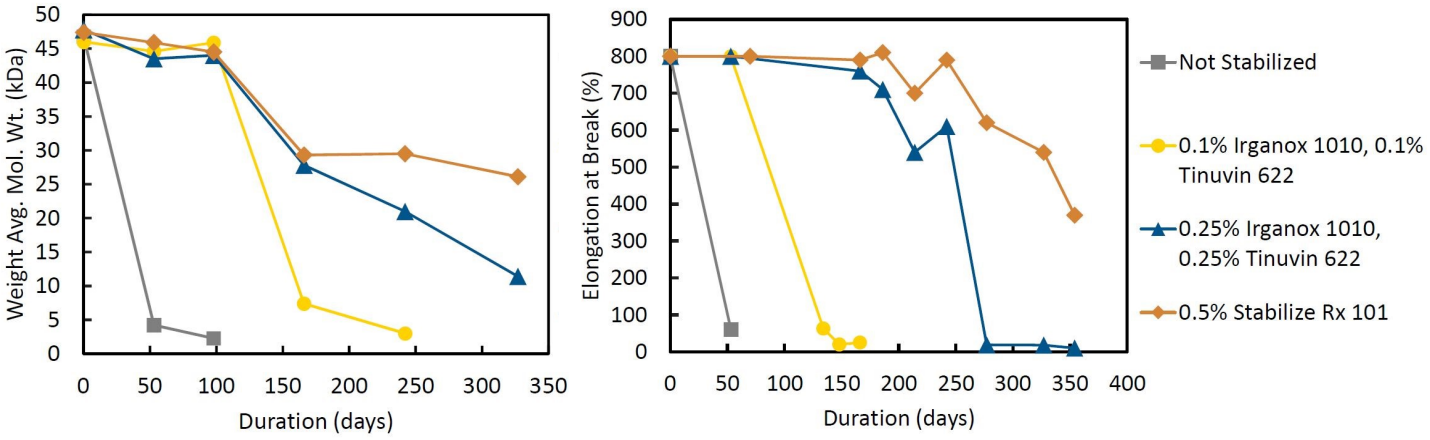


Figure 1. Weight average molecular weight (M_w) and tensile elongation at break of 55shD PEBA with various stabilization packages aged under UV lamp at 23°C.

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