Polyethyleneterephthalate

Toxicological Data on the Unburnt Ingredient

Polyester Bicomponent fibre, commonly known as polyethylene terephthalate (PET) has been widely used in medical devices such as sutures, as well as highly invasive internal implants such as stents, grafts, heart valves, and surgical meshes used to repair tissue defects. A recent biocompatibility report to the US FDA's Centre for Devices and Radiological Health, *Medical Device Material Performance Study: Polyethylene Terephthalate (PET) Safety Profile* (2020), provides an extensive review of safety/toxicity tests for this material, with additional information on reported device failures, the great majority of which were structural failures as opposed to failures related to any sort of toxicological problems arising from such devices.

The report also briefly reviews the non-clinical studies in cells, animals, and human subjects that were evaluated during the FDA's review, and the overall favourable findings that support the FDA's approvals of PET for the use in multiple types of medical devices, including permanently implanted internals devices. Moreover, the FDA has approved PET under 21CFR 177.1630 (polyethylene phthalate polymers).

References:

US FDA Code of Federal Regulations. See http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

PET (polyethylene terephthalate): Medical Device Material Safety Summaries - ECRI Reports