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Gel and Carbon Statement

The primary source of gels is the resin that is supplied to ISOFlex Packaging. Gels are very high molecular weight, MW, portions of the resin that are produced during the production of the resin. These very high MW portions of the resin have a higher melting temperature and, therefore, do not melt along with the remainder of the PE resin. They are PE and not a foreign substance and, therefore, meet the requirements under 21 CFR 177.1520. Some of these gels may also be crossed-linked material that will not melt. These gels will however soften to the point where they will deform and pass through the filters used on the extrusion line to separate out foreign materials.

Carbon specks are typically generated in the extruder and die. Resin manufacturers add anti-oxidants to the resins that are supplied to ISOFlex Packaging to minimize the potential for degradation of the resin from exposure to high temperatures during extrusion. Very small specks of carbon due to this exposure to high temperature may, therefore, be present in the film. These carbon specks are encapsulated in the film and should not be extracted to contaminate the package. Due to the line speed the speck may not be evident to the production personnel.

Keith VanHulle

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Technical Director - Corporate