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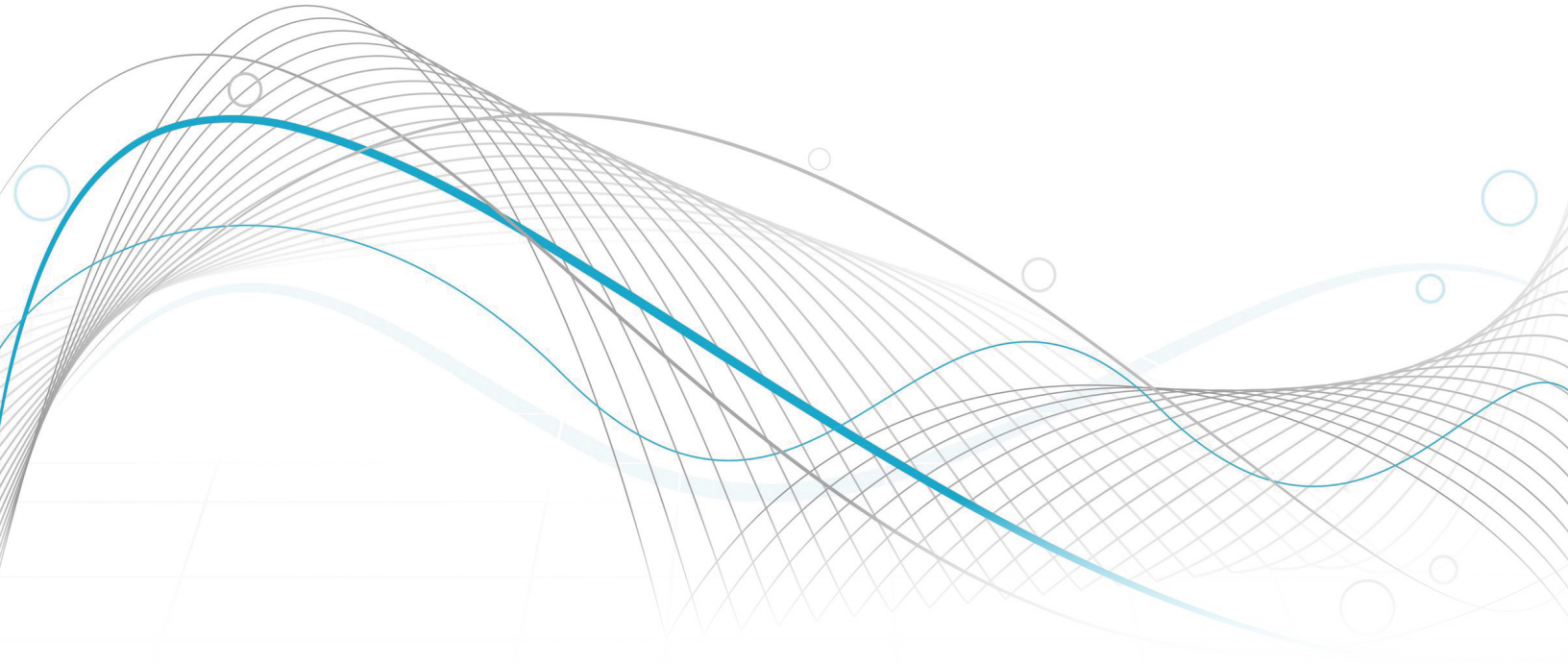

Regulatory Compliance

for Medical Device Materials

REGULATORY SUPPORT & SERVICES

The building blocks of advanced medical devices are polymers tailored to achieve specific performance properties. For nearly three decades, Foster Corporation has been a leading supplier of these custom compounds for medical applications, blending standard polymers with performance additives or other polymers to achieve properties specific to each device. Our services include formulation, prototype quantities, production and regulatory support.

The Foster Regulatory Department is available to assist with regulatory compliance documentation, and supporting documents for FDA and other device approval submissions including but not limited to Safety Data Sheets (SDS), REACH, ROHS, Conflict Minerals, Latex, BPA, Phthalates, Animal Origin, and FDA 21 CFR. Our pre-market support and documentation can assist in material selection in order to streamline the design and regulatory submission process. Post-market compliance documentation is available to support the marketing and distribution of medical devices throughout the world.

MEDICAL DEVICE MATERIAL CONSIDERATIONS

PIGMENTS

Colored polymers play a vital role in the identification, differentiation and aesthetics of medical devices. The FDA provides a list of pigments suitable for polymers used in the manufacture of these devices in Title 21 of the Code of Federal Regulations (21CFR), sections 73 and 74, subpart D. Foster offers 9 of these pigments for extrusion and injection molding applications. Medical device manufacturers may also use food packaging pigments listed in 21 CFR parts 174 through 179 when a specific color is not attainable using pigments listed in 21CFR 73 and 74. However, use of these pigments often requires additional documentation and testing for regulatory approval.

MATERIALS OF ANIMAL ORIGIN

Materials of animal origin may induce risk of disease transmission from animals to humans, including brain and nervous system effecting transmissible spongiform encephalopathy (TSE). The Commission of the European Union (EU) has published a directive regarding the use of TSE-relevant animal tissues and products found in medical devices. EU regulations impose additional compliance requirements on medical device manufacturers, including rigorous risk assessment and risk management practices.

REGISTRATION, EVALUATION, AUTHORIZATION AND RESTRICTION OF CHEMICALS (REACH)

REACH is a regulation of the European Union, adopted to protect human health and the environment from specific chemicals. These chemicals, known as substances of very high concern (SVHC), need to be reported if present in a material in concentrations exceeding 0.1% by weight.

RESTRICTION OF HAZARDOUS SUBSTANCES (RoHS)

RoHS was adopted by the European Union to ensure electronics and electrical equipment are not manufactured with high concentrations of hazardous substances. These restrictions are also applicable to medical devices used for in-vitro diagnostics (IVD). Currently RoHS specifies maximum levels for ten restricted materials.

Maximum Levels for RoHS Restricted Materials

Lead (Pb): < 1000 ppm	Polybrominated Diphenyl Ethers (PBDE): < 1000 ppm
Mercury (Hg): < 100 ppm	Bis(2-Ethylhexyl) phthalate (DEHP): < 1000 ppm
Cadmium (Cd): < 100 ppm	Benzyl butyl phthalate (BBP): < 1000 ppm
Hexavalent Chromium: (Cr VI) < 1000 ppm	Dibutyl phthalate (DBP): < 1000 ppm
Polybrominated Biphenyls (PBB): < 1000 ppm	Diisobutyl phthalate (DIBP): < 1000 ppm

CONFLICT MINERALS

The United States Dodd-Frank Act (section 1502) requires companies to identify and disclose minerals sourced from the Democratic Republic of Congo and adjoining countries. Trade of these minerals have been known to fund conflict in the region resulting in a humanitarian crisis. Applicable minerals include cassiterite (for tin), wolframite (for tungsten), coltan (for tantalum), and gold ore. Tungsten and tantalum are often utilized in medical device applications.

CARCINOGENIC AND TOXIC CHEMICALS

The Safe Drinking Water and Toxic Enforcement Act of 1986 (originally known as Proposition 65) requires the state of California to publish a list of chemicals known to cause cancer or birth defects or other reproductive harm. This list currently includes 800 chemicals.

LATEX

The United States Code of Federal Regulation (21 CFR 801.437) requires labeling of all devices, including device packaging, that contain natural rubber and are intended for contact with humans. Natural rubber includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation. Natural rubber latex proteins have been associated with anaphylaxis, a severe allergic reaction, in some individuals.

BISPHENOL A (BPA)

BPA is an industrial chemical that has been used to make certain polymers, including polycarbonate and epoxy. Some research has shown that BPA can seep into food or beverages from plastic containers and affect health, particularly in fetuses and infants.

PLASTICIZERS

Phthalates are chemical plasticizers used to soften some plastics, such as polyvinyl chloride (PVC). Phthalates are not chemically bound to the plastics and may be susceptible to extraction or leaching. The FDA has issued an advisory risk for DEHP, a common plasticizer for PVC, due to concerns related to reproduction.

Common Plasticizers

DBP (dibutyl phthalate)	DEHP (di 2-ethylhexl phthalate)
DnOP (di-n-octyl phthalate)	DiDP (diisodecyl phthalate)
DiNP (diisononyl phthalate)	DnHP (di-n-hexyl phthalate)
BBP (benzyl butyl phthalate)	DIBP (diisobutyl phthalate)

Foster provides full product documentation and guidance regarding the above product stewardship concerns.

FOSTER COMMITMENT TO QUALITY

Our mission is to remain the industry leader in the design and manufacture of critical polymers and compounds by providing our customers with defect-free, cost-effective, highly-engineered materials in a timely manner. We accomplish this through innovative development of new materials, employment of advanced manufacturing processes, employment of a dedicated staff trained in excellence at all levels, maintaining our customer-oriented focus, and adherence to rigorous quality, safety, and environmental standards.

The Foster Quality Management System is registered to ISO 13485: 2003 and ISO 9001: 2008.

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