



January 1st, 2023

To Our Customers,

**Subj.: FDA, EU, USP REGULATORY STATEMENT**

**The following information refers to the status of Kortrax® under the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) Regulations:**

1. Kortrax® as shipped by BP Polymers, LLC (BPP) meets the requirements for polyamide resins intended for food packaging applications as described in FDA regulations 21 CFR 177.1500 for polyamide 6;
2. Kortrax® may be used in contact with all types of food as defined in Table 1, 21 CFR 176.170(c) at use conditions A-H as defined in Table 2, 21 CFR 176.170(c). Also as defined in 21 CFR 175.300;
3. Kortrax® is produced in accordance with ISO 9001:2015, i.e., support development of materials and processes for the for the plastics industry.
4. Kortrax® does not contain intentionally added PFAS, PFOS compounds.
5. All components of Kortrax® are in compliance with the inventory listing requirements of the U.S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.

**The following information regarding the status of Kortrax® under European Union (EU) regulations is provided below:**

1. Kortrax® is compliant with European Commission (EC) Regulation No. 20/2011;
2. Kortrax® is compliant with REACH Regulation EC 1907/2006/168 Substances of Very High Concern (SVHC). There are no components in Kortrax® that are listed in the inventory of SVHC.

**The following information refers to the status of Kortrax® under United States Pharmacopeia (USP) regulations for plastic packaging systems:**

1. Kortrax® included in High Density Polyethylene (HDPE) containers meets USP Regulation 661 for HDPE Containers.

Regards,

*Kevin Callahan*

Kevin J. Callahan  
Chief Operating Officer  
BP Polymers, LLC