



January 1st, 2022

To Our Customers,

Subj.: FDA, EU, USP FOOD CONTACT COMPLIANCE

The following information on the status of Kortrax® (Pat. Pend.) under the Food and Drug Administration (FDA) regulations is provided below:

1. Kortrax® (Pat. Pend.) as shipped by BP Polymers, LLC (BPP) meets the requirements for Nylon resins intended for food packaging applications as described in FDA regulations 21 CFR 177.1500;
2. Kortrax® (Pat. Pend.) 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. This product is produced in accordance with good manufacturing practices (GMP) as outlined in 21 CFR 174.5.
4. Kortrax® is free of PFOS, PFAS compounds. And Kortrax® is not a nano-composite resin.

The following information on the status of Kortrax® (Pat. Pend.) under European Union (EU) regulations is provided below:

1. Kortrax® (Pat. Pend.) as shipped by BPP meets European Commission (EC) Regulation No. 20/2011;
2. Kortrax® (Pat. Pend.) as shipped by BPP meets REACH Regulation EC 1907/2006/168 Substances of Very High Concern (SVHC).

The following information on the status of Kortrax® (Pat. Pend.) under United States Pharmacopeia (USP) regulations for plastic packaging systems is provided below:

1. Kortrax® (Pat. Pend.) as shipped by BPP and 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