



January 1st, 2024

To Our Customers,

**Subj.: FDA, EPA, CONEG/TPCH, EU, USP, REGULATORY STATEMENT**

**The following information refers to the status of Kortrax® under FDA, EPA, CONEG/TPCH, and ISO compliance requirements:**

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 21 CFR 175.300, 177.1390, 177.1395, and 177.1500.
3. Kortrax® is produced in accordance with ISO 9001:2015, i.e., support development of materials and processes for the plastics industry.
4. The non-detection of PFAS in Baritainers® made with Kortrax® is consistent with the EPA BEAD's Analytical Chemistry Branch's results. Per the EPA, "The acceptability of the new container type is confirmed."
5. All components of Kortrax® comply with the inventory listing requirements of the U.S. Toxic Substances Control Act (TSCA) Chemical Substance Inventory.
6. Kortrax® is not intentionally manufactured with nor does it contain the heavy metals antimony, arsenic, barium, cadmium, hexavalent chromium, lead, mercury, nickel, selenium, or silver in levels exceeding the limits set under CONEG regulations and therefore is TPCH compliant. The cumulative sum concentration of cadmium, hexavalent chromium, lead, and mercury does not exceed 100 ppm.

**The following information regarding the status of Kortrax® under ECHA regulations is provided below:**

1. Kortrax® is compliant with European Commission (EC) Regulation No. 10/2011.
2. Kortrax® is compliant with REACH Regulation EC 1907/2006/168 Substances of Very High Concern (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  
COO  
BP Polymers, LLC

1020 Carrington Place,  
Ste. 2  
Charlottesville, VA 22901

[www.bppolymers.com](http://www.bppolymers.com)  
O: 949-380-1611