

Regulatory Affairs Product Stewardship Information/Certification Data Sheet (RAPIDS)



Pro-fax ST611M

This product is manufactured by Taiwan Polypropylene Co., Ltd. (TPP).

Chemical Inventories/Toxic Substances Control Act

All ingredients in this product are in compliance with the following chemical inventories:

- United States: Toxics Substances Control Act Inventory (TSCA)
- Canada: Domestic Substances List (DSL)
- Europe: European Inventory of Existing Commercial Chemical Substances (EINECS)
- Australia: Australian Inventory of Chemical Substances (AICS)
- Japan: Japanese Existing and New Chemical Substances (ENCS)
- China: Inventory of Existing Chemical Substances in China (ICCS)
- Korea: Korean Existing Chemicals List (KECL)
- Philippines: Philippines Inventory of Chemicals and Chemical Substances (PICCS)
- Taiwan: Toxic Chemical Substances Control Act

This product has no special requirements under US TSCA (e.g. consent orders, test rules, 12(b) requirements, etc.).

US Food and Drug Administration (FDA)

The base resin in this product meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.1520(a)(3)(i) and (c)3.1a. According to our information, all other ingredients used in this product meet the requirements of their respective FDA regulations and 21 CFR 177.1520(b). This product meets the FDA criteria in 21 CFR 177.1520 for food contact applications, excluding cooking, listed under conditions of use C through H in 21 CFR 176.170(c), Table 2. This product can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1.

European Union (EU) Food Contact

The base resin in this product meets the requirements in European Union Directive 2002/72/EC as the monomer(s) is(are) listed without any limitations. The additives are in compliance with 2002/72/EC; however, one additive has a specific migration limit (SML) of 5 ppm, and a process aid has a SML of 6 ppm.

To fully comply with food regulations in Europe, the overall migration as specified in 2002/72/EC from the final article to food can be no greater than 10 mg/dm². The overall migration is determined using the procedures in Directives 97/48/EC (amending 82/711/EC) and 85/572/EC for the intended uses. In addition, the migration of the component(s) mentioned above must be checked to ensure compliance to the SML(s). This is the responsibility of the manufacturer of the final article. In order to obtain the identity of the component(s) with SML(s), a secrecy agreement will need to be established between TPP and the manufacturer of the final article. In addition, we remind you that the manufacturers of the final article must verify that the final article, manufactured according to good manufacturing practices, does not modify the organoleptic properties of the food.

Tallow

Tallow is not used in the manufacture of or the formulation of this product. However, tallow derived additives may be used in the manufacture of this product.