

PLASKOLITE

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April 23, 2020

RE: FDA Regulation 21 CFR § 177.1580

To Whom It May Concern:

Plaskolite's TUFFAK FD Polycarbonate Clear Sheet is produced using Makrolon 3158 000000, Makrolon 3158 550042 or Makrolon 3158 550115 polycarbonate resin. These resins are in chemical compliance with FDA regulation 21 CFR § 177.1580 (Polycarbonate resins) and with applicable FDA regulations for food contact applications under conditions of use B through H, subject to the limitations of 177.1580 and any other applicable regulation.

In addition, Makrolon 3158 000000, Makrolon 3158 550042 and Makrolon 3158 550115 polycarbonate resins are also NSF certified products currently listed under NSF/ANSI Standard 51, Food Equipment Materials, for use with all food contact types at a maximum temperature of use of 212°F.

Our NSF resin listing can be found here: <http://info.nsf.org/Certified/Food/Listings>

USP Class VI - If a product passes our standard set of ISO-10993 biocompatibility tests for general medical grades, then it also meets the requirements of USP Class VI. For TUFFAK FD sheet products, only FD Clear A00 Sheet meets biocompatibility requirements for both ISO 10993 and USP Class VI. TUFFAK FD Clear A00 sheet is made with 100% Makrolon 3158 resin which is a general medical grade. All other colored FD sheet products use colorants that are cleared for food contact use but have not been tested for biocompatibility.

We hope that this information is useful to you and provides clarity on Plaskolite's compliance with FDA Regulation 21 CFR § 177.1580. Please contact us at (800)628-5084 if you have any questions related to this matter.

Sincerely,

Plaskolite Product Support Team