

February 3, 2023

Subject: Statement on FDA 21 CFR for Thermo Scientific™ Nalgene™ Catalog Number Series 2126-XXXX and DS2126-0250

Dear Customer,

Per your request, below is the Thermo Fisher Scientific statement on FDA 21 CFR for catalog number series 2126-XXXX and DS2126-0250. These catalog numbers use four raw materials in the manufacture of the bottle, closure, and closure seal ring.

The bottles are manufactured using polypropylene copolymer (PPCO) resin, part number 8-0028-03. The supplier has indicated this PPCO resin meets the FDA requirements outlined in the Code of Federal Regulations 21 CFR 177.1520(a)(3)(i) and (c)3.2a. According to the supplier's information, all other ingredients used in the formulation meet their respective FDA regulations and 21 CFR 177.1520(b). Specifically, this product meets the FDA criteria for food contact including cooking applications. This product can be used for all food types under Conditions of Use A through H listed in 21 CFR 176.170(c), Table 2.

The closures are manufactured using polypropylene (PP) resin, part number 8-0071-06, and a white colorant, part number 8-0099-34. The PP resin supplier has indicated that this resin meets the FDA requirements outlined in the Code of Federal Regulations 21 CFR 177.1520(a)(1)(i) and (c)1.1a. According to the supplier's information, all other ingredients used in the formulation meet their respective FDA regulations and 21 CFR 177.1520(b). Specifically, this resin meets the FDA criteria for food contact including cooking applications. This resin can be used for all food types under Conditions of Use A through H listed in 21 CFR 176.170(c), Table 2. The white colorant supplier has indicated he ingredients the supplier selected to formulate the colorant are either "generally recognized as safe" (GRAS), prior-sanctioned, subject to an effective Food Contact Notification (FCN), or a Threshold of Regulation exemption (TOR), or identified in one or more of the following sections of Title 21 of the Code of Federal Regulations (CFR) published by the U.S. Food and Drug Administration (FDA): Parts 174, 175, 176, 177, 178, 181, 182, 184 and 186. The supplier has not reviewed specific acceptable food types, conditions of use, or any limitations or restrictions of use for the components used in the colorant.

The closure seal rings are manufactured using a thermoplastic elastomer (TPE) resin, part number 8-0005-30. The supplier has indicated that this TPE resin is acceptable for use in food contact applications under 21 CFR 177.1810(b)(3) and holds a Food Contact Notification (FCN). This allows for the resin to be used as a component of articles intended to contact all food types (FDA Food Types I through IX; 21 CFR 176.170 Table 1) and Conditions of Use A through H (21 CFR 176.170 Table 2). The TPE resin supplier has indicated that all of the components used in the manufacture of this resin comply Title 21 CFR 177.1210 and 177.2600, which state extraction testing to be performed on the final article.

Sincerely,



Jessica Garigen
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Labware and Specialty Plastics