

February 14, 2025

**Subject: Statement on Food Contact Compliance for Thermo Scientific™ Nalgene™ Catalog
Number Series 2114-00XX and 312114-00XX**

Dear Valued Customer:

Per your request, below is the Thermo Fisher Scientific statement on food contact compliance for Nalgene catalog number series 2114-00XX and 312114-00XX. These products are marketed for laboratory use and are not tested to food contact standards; however, the raw material suppliers have provided information about their conformance to food contact requirements. Thermo Fisher Scientific manufacturing uses two raw materials in the production of these bottles and closures.

The bottles are manufactured using high-density polyethylene (HDPE) resin, part number 8-0042-31. The HDPE resin supplier has indicated that the resin complies with the provisions of the United States Federal Food, Drug and Cosmetic Act which are applicable to the resin, and all applicable Food and Drug Administration (FDA) regulations. Specifically, the resin complies with the specifications contained in the FDA regulation 21 CFR 177.1520 for olefin polymers, para. (c) 3.2a and may thus be used in the United States as an article or component of an article intended for use in contact with food, without food-type restrictions, under Conditions of Use A–H (21 CFR 176.170(c) Table 2). Furthermore, the resin supplier has indicated that the composition of the resin complies with the European Union's food contact regulations, including the Framework Regulation (EC) No 1935/2004, Regulation (EC) No 2023/2006 (GMP) and Regulation (EU) No 10/2011, as amended, Annex I (including Table 1, Union list of authorised substances) and Annex II. In addition, the supplier has indicated that the resin complies with the relevant national regulations of the EU member states and non-EU countries which have adopted the European Union legislation. Certain components of the resin are subject to specific migration limits (SMLs) or other restrictions. In addition, the resin does not contain any intentionally introduced dual-use additives.

The closures are manufactured using polypropylene (PP) resin part number 8-0071-06. The PP resin supplier has indicated that the resin meets the FDA requirements outlined in the Code of Federal Regulations 21 CFR 177.1520(a)(1)(i) and (c)1.1a. All other ingredients used in the formulation meet their respective FDA regulations and 21 CFR 177.1520(b). Specifically, the resin meets the FDA criteria for food contact including cooking applications. The resin can be used for all food types under Conditions of Use A through H listed in 21 CFR 176.170(c), Table 2. Furthermore, the resin supplier has indicated that the resin conforms to sections of Regulation (EC) 1935/2004 on materials intended to come into contact with food. The monomers and additives used to produce the resin are listed in EU Regulation 10/2011 and/or amendments. No monomers with a restriction are used. The resin contains substances subject to specific migration limits (SMLs) of 1, 3.6, and 5 mg/kg. The resin also contains a dual-use additive (CAS 1592-23-0) in its formulation.

Sincerely,



Jessica Garigen
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