

February 17, 2025

**Subject: Statement on Food Contact Compliance for Thermo Scientific™ Nalgene™ Catalog Numbers 2250-0020, 2250-0050 and 2250-0130**

Dear Valued Customer:

Per your request, below is the Thermo Fisher Scientific statement on food contact compliance for catalog numbers 2250-0020, 2250-0050 and 2250-0130. 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 four raw materials in the production of the carboy, closure and closure seal ring.

The carboy is manufactured using polypropylene (PP) resin, part number 8-0071-07. 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)(3)(i) and (c)3.2a. According to the PP resin supplier's information, all other ingredients used in the formulation of the resin 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. In addition, the PP 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 SMLs of 1, 3.6, and 5 mg/kg, and contains a dual use additive (CAS 1592-23-0) in its formulation. The white colorant supplier has indicated that the components of the colorant fall under one of the following categories of substances: (1) GRAS, (2) prior-sanctioned, (3) acceptable for food contact applications based on legal opinion and/or supplier certification (4) subject to an effective food contact notification (FCN), (5) exempt from regulation under 21 CFR 170.39 – Threshold of Regulation (TOR), or (6) identified in one or more of the Title 21 CFR Parts 174-178, 181, 182, 184, and/or 186. Furthermore, the colorant supplier has indicated that the components of the colorant meet the relevant requirements of (EC) No. 1935/2004, the "Framework Regulation", as amended, Commission Regulation (EC) No. 2023/2006 on GMP for materials and articles intended to come into contact with food as amended, and Commission Regulation (EU) No. 10/2011, as amended, or Council of Europe's AP(89)1 Resolution, the French Positive List for Plastic Materials, or the Swiss Ordinance List Annex 6, Part A or B. The colorant contains one or more monomers and/or additive(s) that are regulated with a SML, and one or more dual use additives per Regulation (EC) No. 1333/2008 or as flavorings by Regulation (EC) No. 1334/2008.

The closure is 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 the resin meets the FDA requirements outlined in 21 CFR 177.1520(a)(1)(i) and (c)1.1a. According to the PP resin supplier's information, 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. This resin can be used for all food types under Conditions of Use A-H listed in 21 CFR 176.170(c), Table 2. In addition, the PP 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 SMLs of 1, 3.6, and 5 mg/kg, and contains a dual use additive (CAS 1592-23-0) in its formulation. The white colorant supplier has indicated that the components of the colorant fall under one of the following categories of substances: (1) GRAS, (2) prior-sanctioned, (3) acceptable for food contact applications based on legal opinion and/or supplier certification (4) subject to an effective food contact notification (FCN), (5) exempt from regulation under 21 CFR 170.39 – Threshold of Regulation (TOR), or (6) identified in one or more of the Title 21 CFR Parts 174-178, 181, 182, 184, and/or 186. Furthermore, the colorant supplier has indicated that the components of the colorant meet the relevant

requirements of (EC) No. 1935/2004, the "Framework Regulation", as amended, Commission Regulation (EC) No. 2023/2006 on GMP for materials and articles intended to come into contact with food as amended, and Commission Regulation (EU) No. 10/2011, as amended, or Council of Europe's AP(89)1 Resolution, the French Positive List for Plastic Materials, or the Swiss Ordinance List Annex 6, Part A or B. The colorant contains one or more monomers and/or additive(s) that are regulated with a SML, and one or more dual use additives per Regulation (EC) No. 1333/2008 or as flavorings by Regulation (EC) No. 1334/2008.

The seal ring is manufactured using thermoplastic elastomer (TPE) resin, part number 8-0005-30. The TPE resin supplier has indicated that the resin may be acceptable for use in food contact applications, subject to applicable restrictions, in compliance with the Federal Food, Drug, and Cosmetic Act, and all applicable regulations of the U.S. Food and Drug Administration (FDA) as outlined in Title 21 Code of Federal Regulations. All components used in the manufacture of this product comply with Title 21 CFR 177.1210 and 177.2600, which state extraction testing to be performed on the final article. The finished articles are to contact foods only under FDA's Conditions of Use A,B,C,D,E,F,G,H; as described by the FDA. The resin also utilizes a white mineral oil (cleared for use in food and in food-contact articles) which does not fall under the mineral oil dosage limitation found within 21 CFR 177.2600. The supplier indicated that the resin contains and additive, which when used in packaging materials is not considered a food additive by virtue of a "prior sanction". The restriction on its use in this case is that the antioxidant may not migrate to food in an amount to exceed a concentration of 0.005 percent in the food. Dilauryl Thiodipropionate is "generally recognized as safe" when used as an antioxidant in edible fats and oils, provided the total quantity of all antioxidants present does not exceed 0.02 percent. In addition, the TPE resin supplier has indicated that the resin may be acceptable for use in food contact applications, subject to applicable restrictions, in compliance with the harmonised legislation in place in the European Union (EU); including Regulation (EU) 10/2011 on plastic materials and articles intended to come into contact with food is a specific measure within the meaning of Regulation (EC) No. 1935/2004. The supplier further indicated that the resin meets the relevant requirements of European Union regulations 2023/2006 on materials and articles intended to come into contact with food. In addition, all additives and any polymers (excluding polymeric additives which are regulated as additives) that may be present in the resin are compliant with the relevant requirements of EU regulation 10/2011 as amended by EU regulations 321/2011, 1282/2011, 1183/2012, 202/2014, 865/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37, 2019/988, 2019/1338, 2020/1245, 2023/1442 and 2023/1627 on plastic materials and articles intended to come into contact with food (which repeals directive 2002/72/EC as amended). Furthermore, the resin contains four components with listed SMLs of ND (less than 1.0 mg/kg in the final product), 3.6 mg/kg, 5 mg/kg, and 5 mg/kg (SML(T)), respectively. The resin also contains 1 mg/kg of a component with QM, and also contains one dual use additive.

Sincerely,



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