Nalge Nunc International Corporation,
a part of **Thermo Fisher Scientific Inc.**
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March 15, 2024

Subject: Statement on Animal Derived Components for Thermo Scientific™ Nalgene™ Catalog Number Series 2019-XXXX, including 2019-0030, 2019-0060, 2019-0125, 2019-0250, 2019-0500, 2019-1000 and 2019-2000

Dear Customer:

Per your request, below is the Thermo Fisher Scientific statement on the use of animal derived components in manufacturing Nalgene catalog number series 2019-XXXX. Thermo Fisher manufacturing uses three raw materials in the production of these bottles and closures.

The bottle is manufactured using PETG resin, part number 8-0001-32. The resin supplier for this PETG resin has indicated that based on their knowledge of the raw materials and processes used in the manufacture of this PETG resin, they have no reason to expect that animal-derived or bovine-derived materials are present in this PETG resin. The PETG resin supplier has also indicated this PETG resin is not derived from any constituent of animal origin, including ruminants.

The closure is manufactured using high-density polyethylene (HDPE) resin, part number 8-0042-01, and white colorant, part number 8-0099-34. The resin supplier for this HDPE resin has indicated no animal-derived materials are used in the manufacture or formulation of this HDPE resin. The supplier of the white colorant has indicated that at least one raw material used to formulate the concentrate may contain tallow derived material from animal sources. The white colorant supplier has indicated to protect against the transmission of spongiform encephalopathies, their suppliers have confirmed that severe processing conditions are used in the manufacture of these raw materials. In the United States, tallow derivatives are not considered specific risk material or prohibited cattle material as defined by the U.S. Food and Drug Administration in 21 CFR 189.5, Prohibited cattle materials and 21 CFR 700.27, use of prohibited cattle materials in human food and cosmetic products (Docket No. FDA–2004–N–0188). The white colorant supplier has indicated furthermore, their suppliers have certified that these derivatives have undergone a series of process steps in which they are subject to temperatures and pressures sufficient to inactivate BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy) transmitters. These conditions also meet the conditions of the EMA/410/01 rev3, FDA guidance on Medical Devices Containing Materials Derived from Animal Sources and/or ISO 22442-1 Annex C.5.

Thermo Fisher Scientific does not reserve production equipment for raw materials that are free of animal origin ingredients. All resins and colorants used at the manufacturing site comply with the latest revision of EMA/410/01 rev. 3 2011/C73/01 Section 6.4.

Sincerely,

Jennifer L. Voss

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