



Nalgene PET square media bottles

Product regulatory guide

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Thermo Fisher Scientific hereby certifies that the catalog numbers identified in section 1 are manufactured and/or distributed according to the requirements of product and quality specifications as maintained in our quality management system.

ISO Certificate link:

<https://www.thermofisher.com/us/en/home/technical-resources/manufacturing-site-iso-certifications.html>

Product information contained within this document is provided to the best of our knowledge and belief, but without obligation or liability. It is accurate at the date of release, but subject to change. This product regulatory guide is not a product warranty statement or recommendation for product usage. Any validation information or advice provided by Thermo Fisher Scientific herein is for reference purposes only, and does not relieve customer or users of their responsibility for determining the suitability of our products for the customer's or user's intended use. This regulatory guide is not a substitute for any part of the customer's or user's own internal validation, nor may the validation information contained herein be submitted to regulatory bodies.

Date: March 02, 2022

How to use this guide

Scope of this publication

This Product Regulatory Guide (PRG) offers a wealth of material formulation and regulatory information for Thermo Scientific™ Nalgene PET Square Media Bottles. As of the date of this publication, the information provided is current and correct.

The Materials of Construction Table contains product catalog numbers and the corresponding component part numbers and material descriptions.

The Key Product Specification Table includes (where applicable):

- Legal Manufacturer
- Shelf Life
- Product Release Testing
- Sterilization Information
- Certifications such as ISO 10993 compliance, USP 37 <661> Plastic Packaging Systems and Their Materials of Construction, USP <85> Bacterial Endotoxin Test and USP 37 <88> Biological Reactivity Tests compliance.

The Material Information Sheets (MIS), one for each of the component part number that is used in the manufacturing of the finished goods (resins, colorant, liners, closures, etc.), contain extensive formulation and regulatory information for the applicable component.

How to Assess Regulatory Compliance for a PRODUCT Using the Product Regulatory Guide

- 1) Search the left column of the Materials of Construction table for the catalog number of interest.
- 2) The relevant component part number(s) used in the manufacture of the catalog number of interest are listed in the component part number column of the Materials of Construction table. Review the corresponding Material Information Sheets (MIS) for all of the applicable component parts. To fully assess the regulatory compliance for the product of interest, the regulatory information for all applicable components must be assessed.

Materials of construction

Catalog Number	Material Information	
	Component Part Number	Description
342040-XXXX	8-0003-31	PET Bottle Resin
	8-0042-01	High Density Polyethylene (HDPE) Closure Resin
342044-XXXX	8-0003-31	PET Bottle Resin
342141-0384	8-0042-01	High Density Polyethylene (HDPE) Tamper-evident Closure Resin
	8-0042-01	High Density Polyethylene (HDPE) Closure Resin
342178-0240	1-1803-42	Silicone-PTFE Liner in Septum Closure
	8-0042-01	High Density Polyethylene (HDPE) Closure Resin
342178-0384	1-1803-43	Silicone-PTFE Liner in Septum Closure
	8-0042-01	High Density Polyethylene (HDPE) Closure Resin

For compliance, please review all attached Material Information Sheets (MIS) associated with the component parts listed in Table 1 for your NNI finished good. Please note: Full finished goods compliance can only be claimed if each component part used in the manufacture is documented as being compliant.

Key product specifications

Legal Manufacturer		
Nalgene Nunc International Corporation, A part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive, Rochester, NY 14625		
Shelf-Life	5 (five) years	
Product Release Testing		
Visual Inspection	Visual inspection is performed on product samples collected at regular intervals throughout each production run.	
Dimensional Inspection	Dimensional inspection is performed on product samples collected at regular intervals throughout each production run.	
Pyrogenic Testing	These products are certified to be non-pyrogenic at a level <0.5 EU/mL per USP <85>.	
Performance Inspection (Leak Testing)	Performance inspection is performed on product samples collected at regular intervals throughout each production run.	
Leak Tested at 10 psig for 2 minutes	342040-XXXX 342044-XXXX 342141-0384	
Additional Product Information		
Sterilization	Irradiated at 19–28 kGy	Irradiated at 20–45 kGy
	342141-0384	342040-XXXX
	342178-0240	342044-XXXX
	342178-0384	
Product is gamma irradiation sterilized and has a sterility assurance level (SAL) of 10 ⁻⁶ . Product is dosimetric released per ANSI/AAMI/ISO 11137 guidelines.		
Certifications	Representative sampling from this product family.	
	Exclusion—Silicone-PTFE septum material.	
	Product samples irradiated at 19–28 kGy and 20–45 kGy met the requirements of the following tests:	
	• ISO 10993-5:2009(E) Biological evaluation of medical devices Part 5: Tests for <i>In Vitro</i> cytotoxicity	
	• USP 37 <88> Biological Reactivity Tests and ISO 10993-6:2007, Biological evaluation of medical devices Part 6: Tests for local effects after implantation	
	• USP 37 <661> Plastic Packaging Systems and Their Materials of Construction	
	• ISO 10993-3:2003 Bacterial Mutagenicity Test, Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity	
	• USP <85> Bacterial Endotoxin Test	

Material information sheets

Raw Material Number: 8-0003-31

Raw Material Description: Polyethylene Terephthalate (PET) Resin

This material information sheet (MIS) contains regulatory statements from the raw material supplier. Nalge Nunc International (NNI) provides MIS's to aid in determining compliance of your NNI finished product. Please note: Full finished product compliance can only be claimed if each component part used in the manufacture of the product is documented as being compliant.

Substances of Animal Origin (BSE/TSE)

Regulation 999/2001, as amended	Based on supplier knowledge of the raw materials and processes used in the manufacture of this product, the supplier has no reason to expect that animal-derived or bovine-derived materials are present in this product. The equipment used in the manufacturing process of the product did not come into contact with a substance derived from animal origin.
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Food Contact

Commission Regulation EU 10/2011 (and amendments)	This product complies with the compositional requirements of this regulation for plastics used in food-contact applications. There are specific migration limits of 7.5 mg/kg of food and 30 mg/kg of food. There are no additives subject to restrictions on concentrations in food as a food additive. This product is intended for use to manufacture materials and articles in compliance with the general requirements of Regulation (EC) 1935/2004. This product is produced under good manufacturing practices in compliance with EU Regulation 2023/2006.
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US FDA 21 CFR	Under regulations administered by the U.S. Food and Drug Administration (FDA), this product may lawfully be used as articles or components of articles for use in contact with food subject to provisions of 21 CFR 177.1630. The supplier confirms that the product complies with the compositional requirements of FDA regulations at 21 CFR 177.1630(e)(4)(ii) for the conditions of use described in 21 CFR 177.1630 (f), (g), (h), and (j). Based on results from testing of representative polymers, the supplier expect that articles made under good manufacturing practices will meet the requirements of 21 CFR 177.1630 (f), (g), (h), and (j)(1)(ii)(b). It is manufactured, stored, handled and transported under conditions adhering to 21 CFR 174.5 on general provisions applicable to indirect food additives (i.e., current good manufacturing practices for food contact substances).
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Applicable Regulations

Coalition of Northeastern Governors (CONEG) and TPCH	The supplier does not intentionally add cadmium (Cd), hexavalent chromium (CR (6+)), lead (Pb), or mercury (Hg) in the manufacture or formulation of this product. The supplier does not specifically analyze the product for these substances. The supplier expects that the sum of any trace quantities of lead, mercury, cadmium, and hexavalent chromium are below the legislation limit of 100 ppm.
California Proposition 65	This product does not contain any chemicals known to the State of California to cause cancer, birth defects or any other reproductive harm as of the current Proposition 65 list.

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Raw Material Number: 8-0003-31 (continued)

Regulation (EC) No. 1005/2009 on Substances that Deplete the Ozone Layer	Based on the supplier's knowledge of the raw materials and the manufacturing process, the supplier does not expect substances that deplete the ozone layer to be present in this product. The supplier does not analyze this product for ozone depleting substances (ODS) that are classified as such by this legislation.
Directive 2011/65/EU (Restrictions of Hazardous Substances—RoHS 3), as amended by Commission Delegated Directive (EU) 2015/863	The supplier does not routinely analyze this product for the substances restricted by this regulation. However, the supplier does not expect that these substances would be present in this product above the specified limits: Cadmium (Cd): 0.01%; Mercury: 0.1% (Hg); Lead (Pb): 0.1%; Hexavalent chromium (Cr6+): 0.1%; Polybrominated biphenyls (PBB): 0.1 %; Polybrominated diphenyl ethers (PBDE): 0.1 %; Bis(2-Ethylhexyl) phthalate (DEHP): 0.1%; Benzyl butyl phthalate (BBP): 0.1%; Dibutyl phthalate (DBP): 0.1%; Diisobutyl phthalate (DIBP): 0.1%.
China “RoHS” Regulation	The Ministry of Information Industry published “Administrative Measure on the Control of Pollution Caused by Electronic Information Products,” and the law was signed as Decree No. 39. The supplier does not intentionally add or use lead, mercury, hexavalent chromium, cadmium, polybrominated biphenyl (PBB), and polybrominated diphenyl ether (PBDE). The supplier does not specifically analyze the product for these substances. The supplier confirms that the listed materials are not used in the manufacture of this product.
REACH EC/1907/2006 and Substances of Very High Concern (SVHC), Annex XIV and XVII	The supplier confirms that the product does not contain any of the substances included on the current Candidate List of Substances of Very High Concern (SVHC) under REACH. There is no presence of SVHCs above 0.1% in the product or substances from the Annex lists. Nor have any of these substances been intentionally added during the manufacture of the product.
Toxic Substances Control Act (TSCA)	This resin was not formulated to contain decabromodiphenyl ether (DecaBDE), phenol, isopropylated phosphate (3:1) (PIP (3:1)), 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP), hexachlorobutadiene (HCBT), or pentachlorothiophenol (PCTP).
Directive 94/62/EC, Packaging and Packaging Waste (amended by 2004/12/EC, 2005/20/EC, and Regulation (EC) No 219/2009	This statement covers the following heavy metals (or their compounds): Cadmium (Cd), Hexavalent chromium (Cr (6+)), Lead (Pb), Mercury (Hg). Based on the supplier's knowledge of the raw materials and the manufacturing process, it is unlikely that any of these elements would be present in this product in concentrations exceeding the legislation limits.
EU Directive 2012/19/EU, 2002/96/EC—Waste Electrical and Electronic Equipment (WEEE), as amended	The supplier has no reason to expect that this product would contain substances that will obstruct the reuse, recycling or other forms of recovery of the waste of electrical and electronic waste.
Regulation 2005/1895/EC (Epoxy Derivatives), as amended	This product complies with Regulation 2005/1895/EC, which amended Directive 2002/16/EC. The following epoxy substances, 2,2-bis(4-hydroxyphenyl) propane, bis(2,3-epoxypropyl) ether (or BADGE), [and derivatives BADGE.H2O, BADGE.HCl; BADGE.2HCl; BADGE.H2O.HCl]; bis(hydroxyphenyl)methane, bis(2,3-epoxypropyl) ethers (or BFDGE [and derivatives BFDGE.H2O, BFDGE.HCl; BFDGE.2HCl; BFDGE.H2O.HCl]; Novolac glycidyl ethers (NOGE) are not used as a raw material, nor are they added to the manufacturing process of this product. The supplier does not conduct specific analysis for these substances.
Directive 2005/84/EC, Commission Decision 1999/815/EC (Phthalates), as amended	No esters of phthalic acid (also known as ortho-phthalic acid or diesters of 1,2-benzenedicarboxylic acid) are used in the manufacture of this product. The listed phthalates, such as, bis(2-ethylhexyl) phthalate (DEHP); dibutyl phthalate (DBP); benzyl butyl phthalate (BBP); di-iso-nonyl phthalate (DINP); di-isodecyl phthalate (DIDP); di-n-octyl phthalate (DNOP) are not used as a raw material, nor are they added to the manufacturing process or the end product. The supplier does not analyze this product for these substances.
Directive 2004/42/EC (Volatile Organic Compounds), as amended	This product is not considered to be a volatile organic compound (VOC), nor does it contain a VOC, as defined in Article 5 of EU Directive 2004/42/EC.

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Raw Material Number: 8-0003-31 (continued)

Consumer Product Safety Improvement Act of 2008	The supplier has not analyzed this product for the following substances: Lead, Di-iso-nonyl phthalate (DINP); Di(2-ethylhexyl) phthalate (DEHP); Dibutyl phthalate (DBP); Di-iso-decyl phthalate (DIDP); Di-n-octyl phthalate (DNOP); Butylbenzyl phthalate (BBP). These substances are not used as a raw material, nor are they added to the manufacturing process or the end product. The supplier has no reason to expect that these substances would be present above the threshold levels in this legislation (>100 ppm for lead; and concentrations >0.1% for the listed phthalates).
Residual Solvents: USP General Chapter <467> Residual Solvents, ICH Guideline Q3C—Solvents (ICH Class 1,2,3 solvents), EMEA Guideline on the Specification Limits for residues of metal catalysts	The resin supplier does not specifically analyze the products for the presence of the listed residual solvents. If any of these solvents were found to be present, the levels would be expected to be below the concentration limit set in the lists (Reference lists at USP General Chapter <467> Residual Solvents; International Conference on harmonization Q3C - solvents (ICH Class 1, 2, 3 solvents); and EMEA Guideline on the Specification Limits for residues of metal catalysts).
ICH Guideline Q3D on Elemental Impurities	The resin supplier does not specifically analyze the product for the presence of elemental impurities.
Conflict Minerals	Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com
Pharmacopoeia	
European Pharmacopoeia	This product meets the requirements of European Pharmacopoeia (EP) 3.1.15 "Plastics for Pharmaceutical Use, Polyethylene Terephthalate for Containers for Preparation not for Parenteral Use".
Allergen Information	
Consumer Protection Act of 2004	This product is not derived from the following materials identified in the Food Allergen Labeling and Consumer Protection Act of 2004 as major food allergens: milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans.
Other	
Genetically Modified Organisms (GMO)	This product is not genetically modified or not derived from a genetically modified organism as defined in Directive 2001/18/EC and Regulations 1829/2003 and 1830/2003, as amended.
Absence of Following Substances and Chemicals:	Bisphenols (BPA, BPS, BPB, BPF) Latex Melamine Nitrates Nitrosamines PVC Perfluorooctane sulfonic acid and its derivatives (PFOS) Plant derived Silicone

Raw Material Number: 8-0042-01**Raw Material Description:
High Density Polyethylene (HDPE) Resin**

This material information sheet (MIS) contains regulatory statements from the raw material supplier. Nalge Nunc International (NNI) provides MIS's to aid in determining compliance of your NNI finished product. Please note: Full finished product compliance can only be claimed if each component part used in the manufacture of the product is documented as being compliant.

Substances of Animal Origin (BSE/TSE)

Regulation 999/2001

No animal-derived materials are used in the manufacture or formulation of this product. This product can be considered free from bovine spongiform encephalopathy (BSE) and other transmissible spongiform encephalopathies (TSE).

Food ContactCommission Regulation EU
10/2011 (and amendments)

The monomer(s) and the additive(s) of this resin are listed in Commission Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and all its amendments. Injection molding polyethylene resins were tested for the overall and specific migration compliance. The tested sample thickness was 0.43 mm (16.9 mils). The surface-to-volume ratio was 2.34 dm² sample single-side contact with 1dl simulant. The samples were tested with 3% acetic acid and with 50% ethanol, for 2 hours at 70°C followed by 10 days at 40°C, and with olive oil for 10 days at 40°C. Typical migration results are below the overall migration limit (OML) and relevant specific migration limits (SML). Based on the use amount and assuming 100% migration from a packaging article into food, SML compliance without testing would be up to 0.07 cm (27 mils) thickness of an article fully made of this resin only. This product does not contain dual use additives that would be a concern in food. This product meets the requirements of Framework Regulation (EC) No. 1935/2004 on materials and articles intended to come in contact with food. This product is produced in accordance with good manufacturing practice (GMP) as outlined in GMP Regulation (EC) No 2023/2006.

US FDA 21 CFR

This product meets the requirements for polyolefin resins intended for food packaging applications as described in the FDA olefin polymer regulations 21 CFR 177.1520(c)3.2a. This resin may be used in contact with all types of food as defined in Table 1, 21 CFR 176.170(c) and at use conditions B-H as defined in Table 2, 21 CFR 176.170(c). This product is produced in accordance with good manufacturing practices (GMP) as outlined in 21 CFR 174.5.

Health Canada "Letter of No
Objection"

A "Letter of No Objection" for this product has been approved by Health Canada. This product may be used as a food-contact article such as bottle, food pail, cap, and casing under and at the temperature of 212 °F (100 °C).

China Standards on
GB 4806.6-2016

This product is listed on GB 4806.6-2016 "Standard on food-contact use plastic resin" Appendix A Table A.1. This product meets the requirements of GB 4806.6-2016 and the requirements of GB 4806.1-2016 General safety requirements for food contact materials and articles. This product is produced in accordance with good manufacturing practice (GMP) as outlined in GB 31603-2015 General hygiene standard on manufacturing food contact materials and articles.

Applicable RegulationsCoalition of Northeastern
Governors (CONEG) and TPCH

No heavy metals (i.e., antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium, or silver) are purposely added to this product in quantities that would violate governmental guidelines. The summation of lead, cadmium, mercury, and hexavalent chromium in this product is less than 20 ppm. This product therefore meets the relevant requirements of the USA CONEG Regulation / Model Toxics in Packaging Legislation.

California Proposition 65

This product does not contain any chemicals known to the State of California to cause cancer, birth defects or any other reproductive harm as of the current Proposition 65 list.

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Raw Material Number: 8-0042-01 (continued)

Toxic Substances Control Act (TSCA) section 6(h)	To the best of the supplier's knowledge this product meets the requirements for Persistent, Bioaccumulative, and Toxic (PBT) substances as restricted under US Code of Federal Regulations title 40, part 751, subpart E—"Regulation of Certain Chemical Substances and mixtures under section 6 of The Toxic Substances Control Act" (TSCA); also substances not used in the formulation: Decabromodiphenyl ether (DecaBDE); Phenol, isopropylated phosphate (3:1) (PIP (3:1)); 2,4,6-Tris(tertbutyl)phenol (2,4,6-TTBP); Hexachlorobutadiene (HCBD); and Pentachlorothiophenol (PCTP)
Clean Air Act (EC) 1005/2009	This product does not contain any of the following substances regulated by the Clean Air Act: <ul style="list-style-type: none"> • Class I or Class II Ozone-Depleting Substances (CAA Section 602) • Hazardous Air Pollutants (CAA Section 112) • Accidental Release Prevention Substances (CAA Section 112(r)) • Volatile Organic Chemicals (CAA Section 111)
Restriction of Hazardous Substances (RoHS 3)—Directive 2015/863/EU, 2011/65/EU and 2002/95/EC	No heavy metals (i.e., antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium, or silver) are purposely added to this product in quantities that would violate governmental guidelines. The summation of lead, cadmium, mercury, and hexavalent chromium in this product is less than 20 ppm. No polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), Deca Brominated Diphenyl Ethers (Deca BDE), or phthalates are intentionally added to this product. This product therefore meets the relevant requirements of the 2015/863/EU, 2011/65/EU and 2002/95/EC (RoHS) Directives and Regulations.
2002/96/EC and 2012/19/EU (WEEE)	This product meets the relevant requirements of this directive.
2000/53/EC (ELV)	This product meets the relevant requirements of this guidance document.
94/62/EC, 2005/20/EC, and 2013/2/EU (Packaging Waste Directive)	This product meets the relevant requirements of this directive.
REACH EC/1907/2006 and Substances of Very High Concern (SVHC) and Annexes XIV and XVII	The supplier confirms that the product does not contain any of the substances included on the current Candidate List of Substances of Very High Concern (SVHC) under REACH. This product does not contain substances restricted under REACH Annex XVII (Restricted Substances List) or subject to authorization under REACH Annex XIV (Authorization List).
ICH Guideline Q3D on Elemental Impurities	The resin supplier states that the product does not intentionally contain the metals described in the ICH Harmonized Guideline for Elemental Impurities Q3D dated March 22 2019 (including Cd, Pb, As, Hg, Co, V, Ni, Ti, Au, Pd, Ir, Os, Rh, Ru, Se, Ag, Pt, Li, Sb, Ba, Mo, Cu, Sn, Cr).
EU Directives 2002/16/EC and 1895/2005	The resin supplier states that the resin does not contain Epoxy derivatives listed in the EU Directives 2002/16/EC and 1895/2005.
Conflict Minerals	Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com

Pharmacopoeia

Pharmacopoeia USP 39 <87>	This product meets the standards set by the United States Pharmacopoeia USP 39 <87> Biological Reactivity Tests, in Vitro.
Pharmacopoeia USP 26 <88>	This product meets the standards set by the United States Pharmacopoeia USP 26 <88> Biological Reactivity Tests, in Vivo- Class VI Plastics - 70°C.
Pharmacopoeia USP 39 <661.1>	This product meets the standards set by the United States Pharmacopoeia USP 39 <661.1> Plastic Materials of Construction—Identification, Physicochemical, Extractable Metals, and Plastic Additives tests.

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Raw Material Number: 8-0042-01 (continued)

European Pharmacopeia	This product meets the requirements of European Pharmacopoeia 3.1.3. 10th edition "Polyolefines" materials used for the manufacture of containers. It also meets the requirements of European Pharmacopoeia 3.1.5 10th edition "Polyethylene with Additives for Containers for Parenteral Preparations and for Ophthalmic Preparations."
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Allergen Information

Consumer Protection Act of 2004	Allergens such as: peanuts, tree nuts, milk, eggs, wheat gluten, soybeans, fish and shellfish are not used as additives or raw materials in the manufacture of this resin.
European Regulation 1169/2011	Allergens, including but not limited to those listed in EU Regulation 1169/2011 such as: peanuts, tree nuts, milk, eggs, wheat gluten, soybeans, fish and shellfish are not used as additives or raw materials in the manufacture of this resin.

Other

Genetically Modified Organisms (GMO)	Not intentionally used as additives or raw materials in the manufacture of this product: the formulation or manufacture of the product.
Kosher/Halal Certification	The supplier of the resin has not made any efforts to certify its polyethylene resin is in compliance with Kosher/Halal guidelines.

Presence of Following Substances and Chemicals	Palm oil derivative
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Absence of Following Substances and Chemicals:	Bisphenol compounds, including: BPA, BPB, BPC, BPE, BPF, BPH, BPS, and BPZ Melamine Natural rubber latex, dry natural rubber, or synthetic latex Nitrites, Nitrates, Nitrosamines, Nitrosamines impurities: N-nitrosodimethylamine (NDMA), N-Nitrosodiethylamine (NDEA), N-diisopropyl nitrosoamine (NDIPA), N-ethyl-N-isopropyl nitrosoamine (NEIPA); or nitrosating reagent NaNO ₂ , Nitrocellulose Poly- and perfluoroalkyl substances (PFAS), (PFOA), and (PFOS) Polyvinyl Chloride (PVC) or copolymers Phthalates, including: DEHP, DBP, BBP, DINP, DIDP, DNOP, DIBP, DMP, and DEP Silicone
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Raw Material Numbers: 1-1803-42 & 1-1803-43**Raw Material Description: Silicone/PTFE Liner
in 342023-XXXX, 342178-XXXX Closures**

This material information sheet (MIS) contains regulatory statements from the raw material supplier. Nalge Nunc International (NNI) provides MIS's to aid in determining compliance of your NNI finished product. Please note: Full finished product compliance can only be claimed if each component part used in the manufacture of the product is documented as being compliant.

Substances of Animal Origin (BSE/TSE)

Regulation 999/2001

The supplier certifies that the raw materials and processes used to produce this liner does not include, nor do they introduce TSE/BSE. No materials were derived from animal sources. The finished liner complies with EU 999/2001 and EMA 410/01.

Food Contact

US FDA 21 CFR

The supplier cannot certify that the liner used to produce the product meet the requirements of 21 CFR for food contact. The supplier does not test nor produce items for use in that area.

Applicable RegulationsCoalition of Northeastern
Governors (CONEG) and TPCP

The supplier certifies that the raw materials used to produce the liner meet the CONEG legislation on heavy metals.

California Proposition 65

This product does not contain any chemicals known to the state of California to cause cancer, birth defects or any other reproductive harm as of the current Proposition 65 list.

Toxic Substances Control Act
(TSCA)

This product was not formulated to contain decabromodiphenyl ether (DecaBDE), phenol, isopropylated phosphate (3:1) (PIP (3:1)), 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP), hexachlorobutadiene (HCBD), or pentachlorothiophenol (PCTP).

Restriction of Hazardous
Substances (RoHS)—Directive
2011/65/EU

The supplier can confirm that none of the restricted hazardous substances referenced in the directive naturally occur in the raw materials or formulations used to manufacture this product.

REACH EC/1907/2006 and
Substances of Very High Concern
(SVHC)

Based on available information from the suppliers of raw materials and the supplier's manufacturing processes, SVHCs included on the current Candidate List of Substances of Very High Concern (SVHC) do not naturally occur in the raw materials or any formulations used in the manufacture of the liners at > 0.1% by weight, nor are they intentionally introduced in the manufacturing process at > 0.1% by weight.

Conflict Minerals

Request for a conflict minerals statement should be directed to:
conflict.minerals@thermofisher.com

OtherPresence of Following Substances
and Chemicals:

Silicone

Absence of Following Substances
and Chemicals:

Bisphenol A (BPA)
Bisphenol S (BPS)
Latex
Melamine
Nitrosamines
Ozone depleting substances as defined by the EPA
PFAS and PFOA
Phthalates
Plant based material
Polyvinyl chloride (PVC)

Document Number: PRGPETBTLREV03

Effective Date: 03-02-2022

 Learn more at thermofisher.com/mediabottles

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thermo scientific