Nalge Nunc International Corporation,
Part of **Thermo Fisher Scientific**
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# Product Regulatory Guide
## Thermo Scientific Nalgene Polycarbonate Biotainer Bottles & Carboys

**Table 1: Materials of Construction**

| Nalge Nunc International (NNI) Catalog Number | Material Information | | Where Used |
|---|---|---|---|
| | Component Part Number | Component Part Description | Size/Capacity |
| **BOTTLES, VIALS and CLOSURES** | | | |
| **3500-05**<br>**3500-20** | **8-0056-35** | Polycarbonate (PC) Resin | Vial: 5 mL and 20 mL |
| | **1-0454-96** | White (PPCO) Closure with Silicone Liner | Closure: 20 mm |
| **3030-42** | **8-0056-35** | Polycarbonate (PC) Resin | Bottle: 125 mL |
| | **1-0449-61** | White (PPCO) Closure with Silicone Liner | Closure: 38 mm |
| **3120-42**<br>**3233-42**<br>**3405-42**<br>**3410-42**<br>**3423-42**<br>**362515-0480 (closure only)** | **8-0056-35** | Polycarbonate (PC) Resin | Bottle: 20 mL – 20 L |
| | **1-0449-41** | White (PPCO) Closure with Silicone Liner | Closure: 48 mm |
| **3405-16**<br>**3410-08** | **8-0056-35** | Polycarbonate (PC) Resin | Bottle: 5 L and 10 L |
| | **8-0042-01** | High Density Polyethylene (HDPE) Resin | Handle |
| | **1-0449-41** | White PPCO Closure with Silicone Liner | Closure: 48 mm |

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***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.***

| **Table 2: Key Product Specifications** | |
|---|---|
| **Manufacturing Location** | **Product Release** |
| Nalgene Nunc International Corporation,<br>part of Thermo Fisher Scientific<br>75 Panorama Creek Drive<br>Rochester, NY 14625 | Nalgene Nunc International Corporation,<br>part of Thermo Fisher Scientific<br>75 Panorama Creek Drive<br>Rochester, NY 14625 |
| **Product Release Testing** | |
| **Visual Inspection** | Visual inspection is performed on samples collected at regular intervals throughout each production run. |
| **Dimensional Inspection** | Dimensional inspection is performed on samples collected at regular intervals throughout each production run. |
| **Performance Inspection (Leak Testing)** | Performance inspection is performed on samples collected at regular intervals during each production run. |
| **Leak Tested at 2 psig for 2 minutes** | 3405-XX<br>3410-XX<br>3423-XX |
| **Leak Tested at 5 psig for 2 minutes** | 3233-XX |
| **Leak Tested at 10 psig for 2 minutes** | 3030-XX<br>3500-XX |
| **Leak Tested at 10 psig for 10 minutes** | 3120-XX |
| **Pyrogenic Testing** | These products are certified to be non-pyrogenic at a level <0.5 EU/mL per USP <85>. |
| **Ink Adhesion Test (to determine adequacy of printed ink adhesion to plastic surface)** | 3030-XX<br>3120-XX<br>3233-XX |
| **Heat Seal Integrity Liner Adhesion Test** | 3405-16<br>3405-42<br>3410-08<br>3410-80<br>3423-42 |
| **Additional Product Information** | |
| **Sterility** | Sterile products are gamma irradiated at 25-40 kGy. Sterility assurance level (SAL): $10^{-6}$ where product has a shelf life or is specified. Product was dosimetric released per ANSI/AAMI/ISO 11137 guidelines. Validation completed with sample products using the fluid path method. |
| **Shelf-Life** | 5 (five) years |
| **Certifications:** | **Representative sampling from this product family irradiated at 25 - 40 kGY, have been evaluated and found to meet the requirements of:**<br>• ISO 10993-5:2009(E) Biological evaluation of medical devices Part 5: Tests for *In Vitro* cytotoxicity<br>• ISO 10993-10:2010 (E) Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization<br>• ISO 10993-11:2006 Biological evaluation of medical devices Part 11: Tests for systemic toxicity |

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| | • ISO 10993-6:2007 Biological Reactivity Tests, Biological evaluation of medical devices Part 6: Tests for local effects after implantation<br>• USP <85> Bacterial Endotoxin Test<br>• USP 38 <661> Physicochemical Tests, MIR, DSC |

Thermo Fisher Scientific hereby certifies that the products identified above are manufactured and/or distributed according to the requirements of product and quality specifications as maintained in our quality management system which is compliant to ISO 13485:2016 (BSI Certificate Number: FM 653694).

*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.*

Note: If additional information is required please email ROCregSupport@thermo.com

Janet Cosgrove
Global Regulatory Manager, Raw Materials and Product Compliance
Laboratory Products Division

Date: April 16, 2020

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# Material Information Sheet

| **Raw Material Number:** 8-0056-35 | **Raw Material Description:** Polycarbonate 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 | The resin does not contain animal-derived materials as intentionally added ingredients or as expected impurities. |
| **Food Contact** | |
| Commission Regulation EU 10/2011 (and amendments) | This product has been formulated and manufactured in accordance with Commission Regulation (EU) No. 10/2011 of January 14, 2011, including its amendments up to Commission Regulation (EU) No. 2019/1338 of August 8, 2019. This material contains two substances which have a specific migration limit of 0.05 mg/kg food. This material contains a substance which has a quantity maximum of 1 mg/kg material and a specific migration limit of ND (i.e., less than 0.01 mg/kg food). The material does not contain any dual use additives. This material may be used in contact with all food types at temperatures up to 100 degrees C. The material has been manufactured in accordance with the relevant requirements of Commission Regulation EC No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food. |
| US FDA 21 CFR | This product complies with the United States Federal Food and Drug Administration (FDA) Code of Federal Regulations 21 CFR 177.1580. Only such adjuvants or minor modifiers that are permitted by this regulation or meet one or more of the following criteria: (1) are generally recognized as safe (GRAS), 21 CFR Part 182 and 184; (2) are used in accordance with prior sanctions or approvals, 21 CFR Part 181; (3) are permitted for such use by applicable regulations in parts 170 through 189 of this chapter. The resin may be used in contact with all food types under Condition of Use B through H as described in Table 2 of the FDA website. |
| **Applicable Regulations** | |
| Coalition of Northeastern Governors (CONEG and TPCH) | The resin does not contain Cadmium (Cd), Hexavalent chromium (Cr), Lead (Pb), or Mercury (Hg). These metals are not intentionally added to this resin by the supplier and it is unlikely that any of these would be present above threshold limits of 0.1% w/w, except for cadmium, 0.01% w/w cadmium, thus satisfying the requirements of the CONEG and TPCH Model Toxics in Packaging Legislation, the California Toxics in Packaging Prevention Act (California Health and Saftey Code, §25214.11-25214.21), and EU Directive 94/62/EC Packaging Regulations for heavy metals, as amended. |
| California Proposition 65 | Nalge Nunc International (NNI) has assessed finished products manufactured using this resin based on the September 13, 2019 list published by the Office of Environmental Health Hazard Assesment (OEHHA: https://oehha.ca.gov/proposition-65). Our evaluation has shown NNI polycarbonate product may contain a chemical known to the state of California to cause reproductive harm. |

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| Clean Air Act (EC) 1005/2009 | This product does not contain any of the substances regulated by the Clean Air Act Regulation (EC) No.1005/2009 of the European Parliament and of the Council on substances that deplete the ozone layer, as last amended as intentionally added components or expected process impurities. |
| Directive 2011/65/EU, 2015/863/EU, and 2017/2102/EU (Restrictions of Hazardous Substances – RoHS), and amendments | The following substances are not used as raw materials in this product, nor are they added during the manufacture process. The supplier does not routinely analyze the product for these substances and have no reason to expect that these substances would be present above the stated limits: Lead (0.1 %); Mercury (0.1 %); Cadmium (0.01 %); Hexavalent chromium (0.1 %); Polybrominated biphenyls (PBBs) (0.1 %); Polybrominated diphenyl ethers (PBDEs) (0.1 %); Bis(2-ethylhexyl) phthalate (DEHP) (0.1 %); Benzyl butyl phthalate (BBP) (0.1 %); Dibutyl phthalate (DBP) (0.1 %); and Diisobutyl phthalate (DIBP) (0.1 %). |
| REACH EC/1907/2006 and Substances of Very High Concern (SVHC), Annexes XIV and XVII | The supplier confirms that the product does not contain any of the 201 substances included on the Candidate List of Substances of Very high Concern (SVHC) under REACH as of July 16, 2019. 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. |
| Heavy Metals (ELV) Directives 2000/53/EC, 2016/774/EC, (and amendments) | This product complies with the applicable requirements of directives 2000/53/EC, 2016/774/EC, and their amendments. The supplier does not intentionally add the following above corresponding threshold limits as components or as expected process impurities: lead (0.1% Pb), mercury (0.1% Hg), cadmium (0.01% Cd), or hexavalent chromium (0.1% Cr). |
| Phthalates (EU) Directive 2005/84/EC | This product meets the requirements of EU Directive 2005/84/EC. No phthalates, including di-(2-ethylhexyl) phthalate (DEHP), di-n-butyl phthalate (DBP), benzyl butyl phthalate (BBP), diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), di-n-octyl phthalate (DNOP), diisobutyl phthalate (DIBP), Di-n-pentyl phthalate (DNPP), and Di-n-hexyl phthalate (DNHP) are intentionally added components to this product or as expected process impurities above the threshold limits of 0.1% w/w each. |
| ICH Guideline Q3C(R6) – Residual Solvents | The resin does not contain residual solvents listed in the ICH Guideline Q3C(R6) – Residual Solvents or intentionally added components above the threshold limit of 0.1% w/w. The resin may contain traces of Methylene Chloride ≤ 0.1% w/w as a residual impurity. The supplier does not specifically analyze the product for the presence of residual solvents. |
| ICH Guideline Q3D on Elemental Impurities | The resin formula does include a Barium-containing compound at a typical %w/w of ≤ 10 ppm. The supplier does not routinely analyze the product for the presence of the elements listed under the *Guideline for Elemental Impurities ICH Q3D* (Ag, As, Au, Ba, Cd, Co, Cr, Cu, Hg, Lr, Li, Mo, Ni, Os, Pb, Pd, Pt, Rh, Ru, Sb, Se, Sn, Tl, and V). However, if any were found to be present, the levels would be expected to be below the threshold limits of 0.1% w/w, except for cadmium, 0.01% w/w cadmium. |
| Conflict Minerals | Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com |
| Directive 94/62/EC, Packaging and Packaging Waste (amended by 2004/12/EC) | This resin does not contain Cadmium (Cd), Hexavalent chromium (Cr), Lead (Pb), and Mercury (Hg). The supplier does not specifically analyze the resin for the presence of these substances. 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 of 0.01% w/w. |

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| **Pharmacopoeia** | |
| US Pharmacopeia – Class VI | This resin meets the standards set by the United States Pharmacopoeia USP Class VI / ISO 10993. |
| **Allergen Information** | |
| Consumer Protection Act of 2004 | This resin 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. |
| EU Regulation 1169/2011, Directives 2000/13/EC, 2003/89/EC, and Section B.01.010.1 (1) of Canadian Regulation C.R.C., c. 870 | The supplier does not deliberately add any substances from these regulations to the product. The supplier does not specifically analyze the product for the presence of these substances. |
| **Other** | |
| Genetically Modified Organisms (GMO) | The supplier does not deliberately add GMOs to the product, nor are such substances present in any of the raw materials used in the manufacture of the product. |
| Presence of Following Substances and Chemicals: | This product contains Phenyl phosphite derivative/s (as antioxidant). |
| Absence of Following Substances and Chemicals: | Artificial Latex<br>Bisphenol S or other (BPA derivatives)<br>Bromine, Chlorine, Iodine (< 0.2% w/w)<br>Catalysts<br>Fluorine (< 0.1% w/w)<br>Latex<br>Melamine<br>Natural Rubber<br>Natural Rubber Latex (NRL)<br>Polyvinyl chloride (PVC)<br>Preservatives<br>Silicone<br>Stabilizers<br>Substances of plant origin<br>Surface/release agents |

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# Material Information Sheet

| **Component Number:**<br>**1-0454-96** | **Component Description:**<br>**Closure with Liner Assembled** |
|---|---|
| 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 | **White Polypropylene Copolymer (PPCO) Closure**: The closure shell is not manufactured with materials that are derived from animals and therefore, do not present the risk of transmitting Bovine Spongiform Encephalopathy ("BSE") or Transmissable Spongiform Encephalopathies ("TSE").<br>**Silicone/PP Closure Liner**: The raw material used to manufacture the PP film for this product is manufactured on a line that does manufacture other materials using tallow-based process aids so it cannot be excluded that trace levels of these substances may be present as a result of this manufacturing process. All tallow-based ingredients used by our supplier are manufactured under process conditions that exceed temperatures>200 deg. C, pressure> 40 Bar and process times > 20 minutes. These process aids would be exposed to similar conditions in our supplier's process and IF the raw material we purchase was exposed to the process aid, it would again be exposed to similar process conditions during our extrusion process. Per EMA/410/01 rev. 3 section 6.4. Tallow derivatives. "Tallow derivatives, such as glycerol and fatty acids, manufactured form tallow by rigorous processes are thought unlikely to be infectious. Such materials manufactured under the conditions at least as rigorous as those given shall be considered in compliance for this Note for Guidance, irrespective of the geographical origin and the nature of the tissues from which tallow derivatives are derived, (-trans-esterification or hydrolysis at not less than 200° C for not less than 20 minutes under pressure) |
| If present, identification of animal and country of origin | The Bovine is sourced from the USA, Canada, and Mexico. |
| **Food Contact** | |
| Commission Regulation EU 10/2011 (and amendments) | **White PPCO Closure**: Complies with Regulation EU 10/2011.<br>**Silicone/PP Closure Liner**: No supplier information available. |
| US FDA 21 CFR | **White PPCO Closure**: The components of the closure comply with the applicable FDA regulations for food contact as described in Title 21 of the CFR. The resins comply with CFR 177.1520 on Olefin polymers and the colorant complies with 21 CFR 178.3297 on Colorants for polymers.<br>**Silicone/PP Closure Liner**: The closure liner material complies with 21 CFR 177.2600 |
| **Applicable Regulations** | |
| Coalition of Northeastern Governors (CONEG and TPCH) | The supplier does not use lead, cadmium, hexavalent chromium, or mercury in the manufacture or formulation of this product. In addition, this product meets the CONEG limitation of 100 ppm for the total incidental content of cadmium, hexavalent chromium, lead, and mercury. |
| California Proposition 65 | The product complies with the State of California Proposition 65 as of May 24, 2018. |
| Regulation (EC) No. 1005/2009 Substances that deplete the Ozone Layer | **White PPCO Closure**: Complies with Regulation (EC) No 1005/2009 Substances that deplete the Ozone layer.<br>**Silicone/PP Closure Liner**: No supplier information available. |

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| Restriction of Hazardous Substances (RoHS 3) - Directive 2015/863/EU, amends Annex II of 2011/65/EU | The closure and liner complies with the (RoHS 3) Directive 2015/863/EU amending Directive 2011/65/EU, which restricts and prohibits the use of certain hazardous substances, including lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl (PBB), polybrominated diphenyl ether (PBDE), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), and diisobutyl phthalate (DIBP). To the best of the suppliers knowledge and based on vendor information, the ingredients does not contain amounts above the acceptable concentraion levels of the listed substances. |
| REACH EC/1907/2006 and Substances of Very High Concern (SVHC) | Based on the information provided by the supplier's raw materials suppliers, no SVHC substances above 0.1% are present in the product listed in the REACH EC/1907/2006 Regulation and the candidate list of substances for inclusion in Annex XIV, as published by ECHA in January 2018. |
| ICH Guideline Q3C(R6) for Residual Solvents | The product does not fall under ICH/Q3C "Impurities: Guideline for Residual Solvents". |
| ICH Guideline Q3D on Elemental Impurities | **White PPCO Closure**: The documentation for the raw materials used to formulate the closure has not been analyzed for the presence of elemental impurities referenced in the International Conference on Harmonisation's ICH Q3D Guideline for Elemental Impurities.<br>**Silicone/PP Closure Liner**: Based on raw material information and review of the manufacturing process, this item contains intentionally added Platinum (Pt). Testing for these elements has not been performed on this product. |
| Directive 94/62/EC, Packaging & Packaging Waste (amended by 2004/12/EC, 2005/20/EC, and Regulation (EC) No 219/2009) | **White PPCO Closure**: Based on representations of the Suppliers of the Materials from which the Goods are produced, the Goods are, on the date of shipment or delivery, in compliance with the relevant heavy metals requirements, and all current applicable amendments, for the CONEG (Coalition of Northeastern Governors) Reduction of Toxics in Packaging Acts, California Toxics in Packaging Prevention (TIPP) Act, and European Union Council Directive 94/62/EC, Article 11.<br>**Silicone/PP Closure Liner**: No supplier information available. |
| Conflict Minerals | Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com |
| **Allergen Information** | |
| Consumer Protection Act of 2004 | **White PPCO Closure**: Based on representations of the suppliers of the resin and additives from which the Goods are produced, the Goods are, on the date of shipment or delivery not manufactured to contain food allergens including: Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans, Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridized strains) and derivatives, Celery/Celeriac and derivatives, Mustard and derivatives, Sesame seeds and derivatives, Sulfur dioxide and/or sulfites, Lupine and derivatives, and Mollusks and derivatives.<br>**Silicone/PP Closure Liner**: No supplier information available. |
| **Other** | |
| Genetically Modified Organisms (GMO) | **White PPCO Closure**: Based on representations of the suppliers of the material from which the Goods are produced, the Goods are, on the date of shipment or delivery, not manufactured to contain materials derived from genetically modified organisms, nor are considered genetically modified organisms.<br>**Silicone/PP Closure Liner**: No supplier information available. |
| Presence of Following Substances and Chemicals: | Anti-block agent(s)<br>Antioxidant<br>Plant origin<br>Platinum (Pt)<br>Silicone<br>Slip agent(s)<br>Synthetic material<br>Talc (as processing aid) |

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| Absence of Following Substances and Chemicals: | Bisphenol A (BPA)<br>Human origin<br>Latex<br>Light Sensitive Material<br>Microbial origin<br>PVC (closure does not contain PVC; no available information for liner) |

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# Material Information Sheet

| **Component Number:** 1-0449-61 | **Component Description:** 38 mm PPCO Cap with Silicone Liner |
|---|---|

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**Substances of Animal Origin (BSE/TSE)**

| | |
|---|---|
| Regulation 999/2001 | **White Polypropylene Copolymer (PPCO) Closure**: The closure contains one or more ingredients (tallow derived) that are derived from beef or pork tallow that is sourced from the USA. The raw material suppliers have certified that these tallow derivatives comply with the European guidance document 2011/C73/01 on animal derivatives entitled "Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products…" Under 2011/C73/01, Section 6.4 regarding Tallow Derivatives, references the following processing conditions:<br><br>*"Tallow derivatives, such as glycerol and fatty acids, manufactured from tallow by rigorous processes are thought unlikely to be infectious and they have been the subject of specific consideration by CPMP and CVMP. For this reason, such materials manufactured under the conditions at least as rigorous as those given below shall be considered in compliance for this Note for Guidance, irrespective of the geographical origin and the nature of the tissues from which tallow derivatives are derived. Examples of rigorous processes are:*<br><br>— *trans-esterification or hydrolysis at not less than 200 °C for not less than 20 minutes under pressure (glycerol, fatty acids and fatty acid esters production),*<br>— *saponification with NaOH 12 M (glycerol and soap production)*<br>— *batch process: at not less than 95 °C for not less than 3 hours,*<br>— *continuous process: at not less than 140 °C, under pressure for not less than 8 minutes, or equivalent,*<br>— *distillation at 200 °C.*<br><br>*Tallow derivatives manufactured according to these conditions are unlikely to present any TSE risk and shall therefore be considered compliant with this Note for Guidance."* 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 cosmetic products.<br><br>**Silicone/Polypropylene Closure Liner**: There are no animal-derived materials used in the production of the silicone used in the liner. The raw material used to manufacture the PP film for this product is manufactured on a line that does manufacture other materials using tallow-based process aids so it cannot be excluded that trace levels of these substances may be present as a result of this manufacturing process. All tallow-based ingredients used by our supplier are manufactured under process conditions that exceed temperatures>200 deg. C, pressure> 40 Bar and process times > 20 minutes. These process aids would be exposed to similar conditions in our supplier's process and IF the raw material we purchase was exposed to the process aid, it would again be exposed to similar process conditions during our extrusion process. Per EMA/410/01 rev. 3 section 6.4. Tallow derivatives. "Tallow derivatives, such as glycerol and fatty |

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| | acids, manufactured form tallow by rigorous processes are thought unlikely to be infectious. Such materials manufactured under the conditions at least as rigorous as those given shall be considered in compliance for this Note for Guidance, irrespective of the geographical origin and the nature of the tissues from which tallow derivatives are derived, (-trans-esterification or hydrolysis at not less than 200° C for not less than 20 minutes under pressure). |
| If present, identification of animal and country of origin | The bovine or porcine tallow is of US origin. |
| **Food Contact** | |
| Commission Regulation EU 10/2011 (and amendments) | **White PPCO Closure**: The PPCO material does not meet the requirements of EU Regulation 10/2011 for food contact, as it contains an additive not included in Annex 1. Every monomer and additive selected to formulate the white color concentrate is listed in the Commission Regulation (EU) No. 10/2011, as amended. The white color concentrate contains one or more monomers and/or additive(s) that are regulated with a specific migration limit. This colorant also contains pigments which are not listed in (EU) No. 10/2011, but are found in Council of Europe's AP(89) I Resolution or are found in the French Positive List for Plastic Materials. On the basis of mutual recognition, it is acceptable to use the material in all other EU Member States. The concentrate contains one or more dual use additives – subject to a restriction in food additives authorized for the manufacture of plastic materials and articles which are also authorized as food additives by Regulation (EC) No 1333/2008 or as flavorings by Regulation (EC) No 1334/2008.<br>**Silicone/PP Liner**: No supplier information available. |
| US FDA 21 CFR | **White PPCO Closure**: The PPCO material meets the FDA requirements outlined in the Code of Federal Regulations 21 CFR 177.1520(a)(3)(i) and (c)3.1a. According to the supplier's information, all other ingredients used in the formulation meet FDA regulations and 21 CFR 177.1520(b). Specifically, this product meets the FDA criteria for food contact, except for cooking, under conditions of use C through H as listed in 21 CFR 176.170(c), Table 2. The ingredients used to formulate the white 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): 178.3297, 177.1620, and 177.1350. The ingredients selected to manufacture this colorant are acceptable to contact food of all types under conditions of use A through H as described in Table 2 of section 176.170(c). Based upon the agreed letdown ratio, the colorant may be used for the production of food contact articles in the United States, provided that the terms and conditions in the applicable FDA regulations, FCNs, prior sanctions, TOR, and GRAS determinations are met and provided the finished food contact article meets any applicable limitations on extractives.<br>**Silicone/PP Liner:** The materials used in the liner are in compliance with 21CFR 177.2600. |
| **Applicable Regulations** | |
| Coalition of Northeastern Governors (CONEG and TPCH) | This product is in compliance with the Coalition of Northeastern Governors (CONEG) and TPCH Model Toxics in Packaging Legislation. |
| California Proposition 65 | **White PPCO Closure**: 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 effective date of September 13, 2019 Proposition 65 revision.<br>**Silicone Liner:** 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 effective date of May 25, 2018. |
| Restriction of Hazardous Substances (RoHS 3) - Directive 2015/863/EU | The closure and liner comply with the (RoHS 3) Directive 2015/863/EU amending Directive 2011/65/EU, which restricts and prohibits the use of certain hazardous substances, including lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl (PBB), polybrominated diphenyl ether (PBDE), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), and diisobutyl phthalate (DIBP). |

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| REACH EC/1907/2006 and Substances of Very High Concern (SVHC) | This product does not contain any of the chemicals listed on the January 9, 2018 EU Candidate List of Substances of Very High Concern. |
| Directive 94/62/EC, Packaging and Packaging Waste (amended by 2004/12/EC, 2005/20/EC, and Regulation (EC) No. 219/2009 | **White PPCO Closure**: This product conforms to the European Commission Directive 94/62/EC (Article 11) and its amendments on packaging and packaging waste.<br>**Silicone/PP Closure Liner**: No supplier information available. |
| ICH Guideline Q3C(R6) for Residual Solvents | **White PPCO Closure**: The supplier does not specifically analyze the product for the presence of residual solvents listed in the ICH guideline Q3C - Solvents. There is potential for a Class II solvent to be present. The supplier believes if any of the solvents were found to be present, the levels will be well below the concentration limit set in the Guideline for Residual Solvents Q3C (R6).<br>**Silicone/PP Closure Liner:** No supplier information available |
| ICH Guideline Q3D on Elemental Impurities | **White PPCO Closure**: The documentation for the raw materials used to formulate the closure has not been analyzed for the presence of elemental impurities referenced in the International Conference on Harmonisation's ICH Q3D Guideline for Elemental Impurities.<br>**Silicone/PP Closure Liner**: Based on raw material information and review of the manufacturing process, this item contains intentionally added Platinum (Pt). Testing for these elements has not been performed on this product. |
| Conflict Minerals | Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com |
| **Allergen Information** | |
| Consumer Protection Act of 2004 | **White PPCO Closure**: The raw materials have been reviewed for any indication that the eight major substances considered allergens per the *Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA);* Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans are present in the raw materials. There was no indication that the above noted allergens and soybean oil, was found.<br>**Silicone/PP Closure Liner**: No supplier information available. |
| Genetically Modified Organisms (GMO) | **White PPCO Closure**: Genetically Modified Organisms (GMO) are present in the raw materials used to formulate this product.<br>**Silicone/PP Closure Liner**: No supplier information available. |
| Presence of the Following Substances and Chemicals: | Aluminum (catalyst residue <50ppm)<br>Antioxidant<br>Calcium carbonate<br>Talc<br>Platinum<br>Silicone<br>Synthetic material |
| Absence of the Following Substances and Chemicals: | **White PPCO Closure:**<br>Bisphenol A (BPA)<br>Latex<br>Melamine<br>Nitrosamines<br>PVC<br>Silicone |

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| | **Silicone/PP Closure Liner:**<br>Bisphenol A (BPA)<br>Latex<br>Light sensitive material<br>Microbial origin<br>PVC<br>Polytetrafluoroethylene (PTFE) |

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# Material Information Sheet

| **Raw Material Number: 8-0042-01** | **Component Part Description: High Density Polyethylene Resin used in 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 | 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 Contact** | |
| Commission 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 $dm^2$ 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). |

Resin #: 8-0042-01
Accurate as of Date: 12-12-2019
Revision 03

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| 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 Regulations** | |
| Coalition of Northeastern Governors (CONEG) | 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, as shipped, does not contain any carcinogens or reproductive toxins presently known by the State of California to cause cancer or reproductive toxicity at a level of exposure subject to the requirements of California Proposition 65. |
| Clean Air Act (EC) 1005/2009 | This product does not contain any of the following substances regulated by the Clean Air Act:<br>• Class I or Class II Ozone-Depleting Substances (CAA Section 602)<br>• Hazardous Air Pollutants (CAA Section 112)<br>• Accidental Release Prevention Substances (CAA Section 112(r)<br>• Volatile Organic Chemicals (CAA Section 111) |
| Restriction of Hazardous Substances (RoHS) - 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 | The supplier confirms that the product does not contain any of the 201 substances included on the Candidate List of Substances of Very high Concern (SVHC) under REACH as of July 16, 2019. The product does not contain substances with intended release and none of its components are included in Annex XVII of Reach. |
| ICH Guideline Q3D on Elemental Impurities | The resin supplier states that the product does not contain any metal impurities at or above the levels described in USP <232> Elemental Impurities Limits Revision Bulletin dated February 1, 2013 (Table 2) or ICH Harmonized Guideline for Elemental Impurities Q3D dated 16 December 2014 (Table A2.2). These metals are not intentionally added in the manufacturing/formulating/finishing processes. |

Resin #: 8-0042-01
Accurate as of Date: 12-12-2019
Revision 03

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| EU Directives 2002/16/EC and 1895/2005 | The resin supplier states that the resin does not contain Epoxy derivatives listed in this directive. |
| Conflict Minerals | To obtain a conflict minerals statement about a Nalgene or Thermo Fisher product send an email 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. |
| Pharmacopeia USP 26 <88> | This product meets the standards set by the United States Pharmacopeia 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. |
| European Pharmacopeia | This product meets the requirements of European Pharmacopoeia 3.1.3. 6th edition "Polyolefines" materials used for the manufacture of containers. It also meets the requirements of European Pharmacopoeia 3.1.5 6th edition "Polyethylene with Additives for Containers for Parenteral Preparations and for Ophthalmic Preparations." |
| **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 as Kosher/Halal or in compliance with Kosher/Halal guidelines. |

Resin #: 8-0042-01
Accurate as of Date: 12-12-2019
Revision 03

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| Absence of Following Substances and Chemicals: | Abietic acid<br>Acrylamide<br>Acrylonitrile or acrylonitrile co-polymers<br>Alkylphenols<br>Alkylphenol Ethoxylates, including nonylphenol ethoxylate and octylphenol ethoxylate<br>Allergens<br>Antibiotics<br>Aromatic amines<br>Asbestos<br>Azo compounds<br>2,2-Bis(4-hydroxyphenyl)propane<br>bis(2,3-epoxypropyl) ether (BADGE),<br>Bis(hydroxyphenyl)methane<br>bis(2,3-epoxypropyl) ether (BFDGE)<br>Novolac glycidyl ethers (NOGE)<br>Biocides<br>Bisphenol compounds, including: BPA, BPB, BPC, BPE, BPF, BPH, BPS, and BPZ<br>Brominated or halogenated flame retardants<br>Butylated Hydroxytoluene (BHT)<br>Butylated Hydroxyanisole (BHA)<br>Tertiary butylhydroquinone (TBHQ)<br>Chlorinated paraffins, Chlorinated hydrocarbons<br>Colorants or pigments<br>Cyanuric acid<br>Chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC), hydrofluorocarbons (HFC)<br>Di(ethylhexyl) adipate (DEHA)<br>Diethyl hydroxyl amine (DEHA)<br>Di(ethylhexyl)maleate (DEHM)<br>Dimethylfumarate (DMF)<br>Dioxins or furans<br>Endocrine disruptors<br>Epoxidised Soybean Oil<br>Formaldehyde<br>Fungicides or fumigants<br>Halogens<br>Hormones<br>Melamine<br>Methyl bromide<br>Mineral Oil Saturated Hydrocarbons (MOSH), Mineral Oil Aromatic Hydrocarbons (MOAH)<br>Natural rubber latex, dry natural rubber, or synthetic latex<br>Nonyl phenol (NP)<br>Organotin compounds<br>Ozone-depleting chemicals<br>Parabens<br>Pesticides and fungicides<br>Poly- and perfluoroalkyl substances (PFAS), (PFOA), and (PFOS)<br>Polyvinyl Chloride (PVC) or copolymers<br>Photoinitiators, including: benzophenone, hydroxybenzophenone, and 4-methylbenzophenone, and Isopropylthioxanthone (ITX) |

Resin #: 8-0042-01
Accurate as of Date: 12-12-2019
Revision 03

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| | Phthalates, including: DEHP, DBP, BBP, DINP, DIDP, DNOP, DIBP, DMP, and DEP<br>Plasticizers<br>Polycyclic aromatic hydrocarbons (PAH), also called polyaromatic hydrocarbons<br>Polybrominated Diphenyl Ethers (PBDEs) included: decaBDE, octaBDE, and pentaBDE<br>Polycarbonates<br>Polychlorinated and Polybrominated Biphenyls (PCBs and PBBs)<br>Polychlorinated and Polybrominated Terphenyls (PCTs and PBTs)<br>Polydimethylsiloxane (PDMS)<br>Radioactive Substances<br>Recycled materials<br>Silicone<br>Slip Agent<br>Solvent Yellow 93 (SY93)<br>Sulfonamides<br>Triclosan (2,4,4'-trichloro-2'-hydroxydiphenylether), Triclocarban<br>Tris-Nonylphenol Phosphite (TNPP)<br>Vinyl Chloride Monomer (VCM) |

Resin #: 8-0042-01
Accurate as of Date: 12-12-2019
Revision 03

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# Material Information Sheet

| **Component Number:** 1-0449-41 | **Component Description:** 48 mm PPCO Cap with Silicone Liner |
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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)**

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| Regulation 999/2001 | **White Polypropylene Copolymer (PPCO) Closure**: The closure contains one or more ingredients (tallow derived) that are derived from beef or pork tallow that is sourced from the USA. The raw material suppliers have certified that these tallow derivatives comply with the European guidance document 2011/C73/01 on animal derivatives entitled "Note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products…" Under 2011/C73/01, Section 6.4 regarding Tallow Derivatives, references the following processing conditions:<br><br>*"Tallow derivatives, such as glycerol and fatty acids, manufactured from tallow by rigorous processes are thought unlikely to be infectious and they have been the subject of specific consideration by CPMP and CVMP. For this reason, such materials manufactured under the conditions at least as rigorous as those given below shall be considered in compliance for this Note for Guidance, irrespective of the geographical origin and the nature of the tissues from which tallow derivatives are derived. Examples of rigorous processes are:*<br><br>— *trans-esterification or hydrolysis at not less than 200 °C for not less than 20 minutes under pressure (glycerol, fatty acids and fatty acid esters production),*<br>— *saponification with NaOH 12 M (glycerol and soap production)*<br>— *batch process: at not less than 95 °C for not less than 3 hours,*<br>— *continuous process: at not less than 140 °C, under pressure for not less than 8 minutes, or equivalent,*<br>— *distillation at 200 °C.*<br><br>*Tallow derivatives manufactured according to these conditions are unlikely to present any TSE risk and shall therefore be considered compliant with this Note for Guidance."* 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 cosmetic products.<br><br>**Silicone/Polypropylene Closure Liner**: There are no animal-derived materials used in the production of the silicone used in the liner. The raw material used to manufacture the PP film for this product is manufactured on a line that does manufacture other materials using tallow-based process aids so it cannot be excluded that trace levels of these substances may be present as a result of this manufacturing process. All tallow-based ingredients used by our supplier are manufactured under process conditions that exceed temperatures>200 deg. C, pressure> 40 Bar and process times > 20 minutes. These process aids would be exposed to similar conditions in our supplier's process and IF the raw material we purchase was exposed to the process aid, it would again be exposed to similar process conditions during our extrusion process. Per EMA/410/01 rev. 3 section 6.4. Tallow derivatives. "Tallow derivatives, such as glycerol and fatty |

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| | acids, manufactured form tallow by rigorous processes are thought unlikely to be infectious. Such materials manufactured under the conditions at least as rigorous as those given shall be considered in compliance for this Note for Guidance, irrespective of the geographical origin and the nature of the tissues from which tallow derivatives are derived, (-trans-esterification or hydrolysis at not less than 200° C for not less than 20 minutes under pressure). |
| If present, identification of animal and country of origin | The bovine or porcine tallow is of US origin. |
| **Food Contact** | |
| Commission Regulation EU 10/2011 (and amendments) | **White PPCO Closure**: The PPCO material does not meet the requirements of EU Regulation 10/2011 for food contact, as it contains an additive not included in Annex 1. Every monomer and additive selected to formulate the white color concentrate is listed in the Commission Regulation (EU) No. 10/2011, as amended. The white color concentrate contains one or more monomers and/or additive(s) that are regulated with a specific migration limit. This colorant also contains pigments which are not listed in (EU) No. 10/2011, but are found in Council of Europe's AP(89) I Resolution or are found in the French Positive List for Plastic Materials. On the basis of mutual recognition, it is acceptable to use the material in all other EU Member States. The concentrate contains one or more dual use additives – subject to a restriction in food additives authorized for the manufacture of plastic materials and articles which are also authorized as food additives by Regulation (EC) No 1333/2008 or as flavorings by Regulation (EC) No 1334/2008.<br>**Silicone/PP Liner**: No supplier information available. |
| US FDA 21 CFR | **White PPCO Closure**: The PPCO material meets the FDA requirements outlined in the Code of Federal Regulations 21 CFR 177.1520(a)(3)(i) and (c)3.1a. According to the supplier's information, all other ingredients used in the formulation meet FDA regulations and 21 CFR 177.1520(b). Specifically, this product meets the FDA criteria for food contact, except for cooking, under conditions of use C through H as listed in 21 CFR 176.170(c), Table 2. The ingredients used to formulate the white 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): 178.3297, 177.1620, and 177.1350. The ingredients selected to manufacture this colorant are acceptable to contact food of all types under conditions of use A through H as described in Table 2 of section 176.170(c). Based upon the agreed letdown ratio, the colorant may be used for the production of food contact articles in the United States, provided that the terms and conditions in the applicable FDA regulations, FCNs, prior sanctions, TOR, and GRAS determinations are met and provided the finished food contact article meets any applicable limitations on extractives.<br>**Silicone/PP Liner:** The materials used in the liner are in compliance with 21CFR 177.2600. |
| **Applicable Regulations** | |
| Coalition of Northeastern Governors (CONEG and TPCH) | This product is in compliance with the Coalition of Northeastern Governors (CONEG) and TPCH Model Toxics in Packaging Legislation. |
| California Proposition 65 | **White PPCO Closure**: 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 effective date of September 13, 2019 Proposition 65 revision.<br>**Silicone Liner:** 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 effective date of May 25, 2018. |
| Restriction of Hazardous Substances (RoHS 3) - Directive 2015/863/EU | The closure and liner comply with the (RoHS 3) Directive 2015/863/EU amending Directive 2011/65/EU, which restricts and prohibits the use of certain hazardous substances, including lead, cadmium, mercury, hexavalent chromium, polybrominated biphenyl (PBB), polybrominated diphenyl ether (PBDE), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), and diisobutyl phthalate (DIBP). |

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| REACH EC/1907/2006 and Substances of Very High Concern (SVHC) | This product does not contain any of the chemicals listed on the January 9, 2018 EU Candidate List of Substances of Very High Concern. |
| Directive 94/62/EC, Packaging and Packaging Waste (amended by 2004/12/EC, 2005/20/EC, and Regulation (EC) No. 219/2009 | **White PPCO Closure**: This product conforms to the European Commission Directive 94/62/EC (Article 11) and its amendments on packaging and packaging waste.<br>**Silicone/PP Closure Liner**: No supplier information available. |
| ICH Guideline Q3C(R6) for Residual Solvents | **White PPCO Closure**: The supplier does not specifically analyze the product for the presence of residual solvents listed in the ICH guideline Q3C - Solvents. There is potential for a Class II solvent to be present. The supplier believes if any of the solvents were found to be present, the levels will be well below the concentration limit set in the Guideline for Residual Solvents Q3C (R6).<br>**Silicone/PP Closure Liner:** No supplier information available |
| ICH Guideline Q3D on Elemental Impurities | **White PPCO Closure**: The documentation for the raw materials used to formulate the closure has not been analyzed for the presence of elemental impurities referenced in the International Conference on Harmonisation's ICH Q3D Guideline for Elemental Impurities.<br>**Silicone/PP Closure Liner**: Based on raw material information and review of the manufacturing process, this item contains intentionally added Platinum (Pt). Testing for these elements has not been performed on this product. |
| Conflict Minerals | Request for a conflict minerals statement should be directed to:<br>conflict.minerals@thermofisher.com |
| **Allergen Information** | |
| Consumer Protection Act of 2004 | **White PPCO Closure**: The raw materials have been reviewed for any indication that the eight major substances considered allergens per the *Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA);* Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans are present in the raw materials. There was no indication that the above noted allergens and soybean oil, was found.<br>**Silicone/PP Closure Liner**: No supplier information available.. |
| Genetically Modified Organisms (GMO) | **White PPCO Closure**: Genetically Modified Organisms (GMO) are present in the raw materials used to formulate this product.<br>**Silicone/PP Closure Liner**: No supplier information available. |
| Presence of the Following Substances and Chemicals: | Aluminum (catalyst residue <50ppm)<br>Antioxidant<br>Calcium carbonate<br>Talc<br>Platinum<br>Silicone<br>Synthetic material |
| Absence of the Following Substances and Chemicals: | **White PPCO Closure:**<br>Bisphenol A (BPA)<br>Latex<br>Melamine<br>Nitrosamines<br>PVC<br>Silicone |

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| | **Silicone/PP Closure Liner:**<br>Bisphenol A (BPA)<br>Latex<br>Light sensitive material<br>Microbial origin<br>PVC<br>Polytetrafluoroethylene (PTFE) |