



Nalgene PETG square media bottles, diagnostic bottles and serum vials

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.

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™ PETG square media bottles, diagnostic bottles and serum vials. 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		Where Used Size/Capacity
	Component Part Number	Description	
Bottles and Closures			
322020-XXXX	8-0001-32	PETG Resin	Bottles: 30mL–2000mL
342020-XXXX	8-0042-01	HDPE Resin	Closures: 20mm–53B dia.
342023-XXXX	8-0001-32	PETG Resin	Bottles: 60mL–1000mL
	8-0042-01	HDPE Resin	Closure:
	1-1803-42 or 1-1803-43	Silicone PTFE Liner	1-1803-42 - 24mm dia. 1-1803-43 - 38mm dia.
342024-XXXX	8-0001-32	PETG Resin	Bottles: 30mL–1000mL
Amber Bottle and Closure			
322021-XXXX	8-0001-32	PETG Resin	Bottles: 30mL–125mL Closures: 20mm–38mm
	8-0099-33	Amber colorant	
	8-0042-01	HDPE Resin	
	8-0097-17	Amber Colorant	
Diagnostic Bottles and Serum Vials			
322030-0010 322032-00XX 342030-XXXX 342032-00XX	8-0001-32	PETG Resin	Serum Vials: 3mL–20mL
2035-00XX 342035-00XX	8-0001-32	PETG Resin	Diagnostic Bottles: 5mL–20mL Closure with foam liner 20mm dia.
	8-0042-01	HDPE Resin	
	8-0099-34	White Colorant	
	1-1860-82	LDPE/HDPE Liner	
342033-0010	8-0001-32	PETG Resin	Serum Vials: 10mL
	8-0099-33	Amber Colorant	
Replacement Closures			
342151-0XXX	8-0042-01	HDPE Resin	Closures: 38mm–45mm
312158-0021	8-0042-01	HDPE Resin	Closure with foam liner 20mm dia.
	8-0099-34	White Colorant	
	1-1860-82	LDPE/HDPE Liner	
312158-0022	8-0042-01	HDPE Resin	Closure with foam liner 20mm dia.
	8-0099-43	Black Colorant	
	1-1860-82	LDPE/HDPE Liner	

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Catalog Number	Material Information (Continued)		Where Used Size/Capacity
	Component Part Number	Description	
342178-0XXX	8-0042-01	HDPE Resin	Closure with silicone liner 24mm–38mm
	1-1803-42 or 1-1803-43	Silicone PTFE Liner	
342141-0384	8-0042-01	HDPE Resin	Tamper Evident Closure: 38mm

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. 236 Perinton Parkway Fairport, NY 14450	Nalgene Nunc International Corporation, A part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive, Rochester, NY 14625
Shelf-Life (Sterile SKUs Only)	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 (Sterile SKUs Only)	Where products have a pyrogen claim, product determined 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. *Not applicable to Crimp vials: 342030-XXXX 322030-XXXX
Leak Tested at 2 psi for 2 minutes	322020-0030, 322020-0060, 322021-0030, 322021-0060, 342020-0030, 342020-2000, 342020-0060, 342024-0030, 342024-0060, 342151-0200, 342151-0240
Leak Tested at 10 psi for 2 minutes	2035-0XXX, 312158-XXXX, 322020-0125, 322020-0250, 322020-0500, 322020-1000, 322021-0125, 322032-XXXX, 342020-0125, 342020-0250, 342020-0500, 342020-1000, 342020-9500, 342023-XXXX, 342024-0125, 342024-0250, 342024-0500, 342024-1000, 342032-XXXX, 342033-0010, 342035-0XXX, 342158-XXXX, 342178-XXXX, 342151-038X, 342141-0384

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Legal Manufacturer (continued)**Additional Product Information****Sterilization Dose -
(Sterile Products only)****Irradiated at 19–28 kGy**

2035-0XXX
342023-XXXX
342030-XXXX
342032-XXXX
342035-0XXX
342151-0380
342158-XXXX
342178-XXXX
342141-0384
342033-0010

Irradiated at 20–45 kGy

342020-XXXX
342024-XXXX
342151-0240
342151-0384

Product Irradiation Sterilized 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.
Sterilization dose audits performed quarterly.

Certifications**Representative product family samples that were irradiated at 45 kGy were tested to and met the requirements to the following standards:**

- ISO 10993-5:2009(E) Biological evaluation of medical devices
Part 5: Tests for *In Vitro* cytotoxicity
- USP 37 <88>; ISO 10993-6:2007 Biological Reactivity Tests, Biological evaluation of medical devices Part 6: Tests for local effects after implantation
- USP 37 <661>; Containers – Plastic
- ISO 10993-3:2003 Bacterial Mutagenicity Test, Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity

Exclusions: Amber products and closure liners not tested

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.

ISO Certificate link:

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

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Material information sheets

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 (EC) No. 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 Regulations

Coalition of Northeastern
Governors (CONEG) and TPCH

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 (HCBT), 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)

This product meets the requirements of REACH EC 1907/2006. The SVHCs identified in the current candidate list do not naturally occur in the raw materials in a concentration above 0.1% w/w for the product, nor are they intentionally introduced in the manufacturing process.

Conflict Minerals

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

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Raw Material Numbers: 1-1803-42 & 1-1803-43 (continued)**Other**

Presence 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)

Raw Material Number: 1-1860-82**Raw Material Description:
LDPE/HDPE liner in closures for bottles
2035-XXXX, 342035-XXXX, 312158-00XX**

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

Animal derived components are not known to be present in the raw materials or introduced during the manufacture of the liner.

Food ContactCommission Regulation
EU 10/2011

The product complies with Regulation (EU) No. 10/2011. The monomers and additives used to manufacture this product are in compliance with the Commission Regulation (EU) No. 10/2011 on plastic materials and articles intended to come into contact with food, as amended.

US FDA 21 CFR

The components of the liner comply with the applicable FDA regulations for food contact as described in Title 21 of the Code of Federal Regulations. The resins comply with 21 CFR 177.1350 on Olefin polymers and the colorant complies with 21 CFR 178.3297 on Colorants for polymers.

Applicable RegulationsCoalition of Northeastern
Governors (CONEG) and TPCH

This product complies with the Coalition of Northeastern Governors (CONEG) requirements for heavy metals contained in the Toxics in Packaging Clearinghouse (TPCH) laws. The sum of the incidental concentrations of lead, cadmium, mercury, and hexavalent chromium present in any packaging material will not exceed 100 ppm by weight and there is no intentional addition of lead, cadmium, mercury, and hexavalent chromium during the manufacturing process.

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.

Substances that deplete
the Ozone layer

The supplier states that the raw materials used to manufacture the liner are neither manufactured with nor contain any "Ozone Depleting Substances" listed by the U.S. Environmental Protection Agency for the protection of the stratospheric ozone (Title VI of the Clean Air Act, and 40 CFR Part 82, Subparts A and E, including chlorofluorocarbons, halons, methyl chloroform, hydrochlorofluorocarbons) and listed in Regulation (EC) No. 2037/2000 (including chlorofluorocarbons, other fully halogenated chlorofluorocarbons, halons, carbon tetrachloride 1,1,1-trichloroethane, methyl bromide, hydrobromofluorocarbons, and hydrochlorofluorocarbons).

Restriction of Hazardous
Substances (RoHS 3) -
Directive 2015/863/EU which
amends Annex II of 2011/65/EU

The product complies with the requirements of the RoHS Directive which restricts and prohibits the use of certain hazardous substances including lead, cadmium, mercury, hexavalent chromium and two bromine-containing flame retardants: PBB (polybrominated biphenyl) and PBDE (polybrominated diphenyl ether). Directive 2015/863 (a/k/a RoHS 3) added four additional restricted substances (phthalates) to the above list of six. The RoHS 3 substances are not knowingly added or used in the manufacturing processes of the product or by the raw material suppliers. Therefore, the product does not contain substances which exceed the threshold limits listed in the EU RoHS 3 directive.

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 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.

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Raw Material Number: 1-1860-82 (continued)

EC 1895/2005 (BADGE, BFDGE, NOGE)	The materials BADGE, BFDGE or NOGE are not intentionally added in this product as referenced in Commission Regulation 1895/2005/EC on the use of certain epoxy derivatives in materials and articles intended to come in contact with foodstuff as plasticizers, additives or raw materials. The supplier, nor the suppliers have specifically analyzed for the presence of the subject compounds. Based on the supplier's knowledge of the raw materials and processes used in the manufacture of the product, the supplier has no reason to expect that these chemicals would be present at any appreciable level.
Directive 94/62/EC, Packaging & Packaging Waste (amended by 2004/12/EC, 2005/20/EC, and Regulation (EC) No 219/2009)	Complies with EU Directive 94/62/EC of Article 11 pertaining to heavy metals in packaging and packaging waste.
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 (HCBT), or pentachlorothiophenol (PCTP).
Conflict Minerals	Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com
Allergen Information	
Consumer Protection Act of 2004	The following eight common allergens (as referred to in the Allergen Labeling and Consumer Protection Act of 2004 – FALCPA), which account for more than 90% of all food allergies are: peanuts, soybeans, milk, eggs, fish, crustacea, tree nuts, and wheat. The supplier has reviewed the ingredients and processing aids used in the production of the products and has determined that the allergens identified by FDA as primary allergens and/or their derivatives are not used as ingredients in the product or in the production of raw materials used in the product.
Other	
Genetically Modified Organisms (GMO)	This product does not contain Genetically Modified Organisms (GMOs).
Absence of Following Substances and Chemicals:	BPA BPS Latex Melamine Nitrosamines PVC Phthalates Plant based material Silicone

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Substances of Animal Origin (BSE/TSE)

Regulation 999/2001

Based on the supplier's 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 resin.

Food Contact

Commission Regulation EU
10/2011 (and amendments)

This resin complies with the compositional requirements of this regulation for plastics used in food-contact applications. The final product must meet the overall migration limit of 60 mg/kg of food or 10 mg/square decimeter of the plastic. There are also specific migration limits for ethylene glycol or diethylene glycol (30 mg/kg of food). Based on data obtained by the supplier, articles produced from this polymer should comply with the applicable overall and specific migration limits when tested with 3% acetic acid, 10% ethanol and simulant D under conditions including 2 hours at 70°C followed by 10 days at 40°C. Regarding the dual use additives provision, there are no additives subject to restrictions on concentrations in food as a food additive. This resin is intended for use to manufacture materials and articles in compliance with the general requirements of Regulation (EC) 1935/2004. This resin is produced under good manufacturing practices in compliance with EU Regulation 2023/2006.

US FDA 21 CFR

Under regulations administered by the U.S. Food and Drug Administration (FDA), this resin may lawfully be used as articles or components of articles intended for use in contact with food subject to provisions of 21 CFR 177.1315(b)(1), and Food Contact Notifications No. 179 and 1234. This product as supplied, complies with the compositional and inherent viscosity requirements of FCN 179 and FCN 1234. FCNs 179 and 1234 provide a wider range of conditions of use than 21 CFR 177.1315. Under FCN 179, this resin may lawfully be used as films or articles or components of films or articles, in either a non-oriented or oriented finished form, intended for contact with foods aqueous, acidic, low (alcohol up to 13% by volume), fatty under Conditions of Use C (hot filled or pasteurized above 150°F) through G (frozen storage—no thermal treatment in the container). FCN 179 also permits use in contact with foods containing up to 25%, by volume, alcohol under conditions of use E (room temperature filled and stored—no thermal treatment in container) through Condition of Use G. FCN 1234 includes the previous Conditions of Use from FCN 179, but additionally allows for use in contact with foods containing up to 50 percent by volume alcohol under Conditions of Use E through G. Based on results from testing of representative polymers, the supplier expects that articles made under good manufacturing practices will meet the relevant requirements of these food contact clearances.

Applicable Regulations

Coalition of Northeastern
Governors (CONEG)

This statement covers the following heavy metals (or their compounds): Cadmium (Cd), Hexavalent chromium (Cr (6+)), Lead (Pb), Mercury (Hg). These metals are not intentionally added to this product by the supplier. Based on testing of representative samples of this product, it is unlikely that any of these elements would be present in this product in concentrations exceeding the legislation limits.

California Proposition 65

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

Continued next page

Raw Material Number: 8-0001-32 (continued)

Regulation EC No. 1005/2009 on Substances that deplete the Ozone layer	The supplier does not analyze this resin for ozone depleting substances (ODS) that are classified as such by this legislation. Based on the supplier's knowledge of the raw materials and of its manufacturing process, they do not expect the listed substances to be present in the product.
40 CFR Part 82 Subpart E, ODS	The supplier confirms resins are neither manufactured with nor contain any "ozone depleting substances" listed by the U.S. Environmental Protection Agency for the protection of stratospheric ozone (Title VI of the Clean Air Act, and 40 CFR Part 82, Subparts A and E, including chlorofluorocarbons, halons, carbon tetrachloride, methyl chloroform, hydrochlorofluorocarbons.) Based on the supplier's knowledge of the raw materials and manufacturing process, these substances may be present in trace quantities in the products.
40 CFR 63 Subpart 112(b)(1), HAP	Section 112(b)(1) of the Clean Air Act defines Hazardous Air Pollutants (HAPs) that are subject to regulation by the United States Environmental Protection Agency. The supplier has not analyzed this product against the entire HAP list. However, based on the supplier's knowledge of the raw materials and manufacturing processes and analyses of representative product samples, the supplier does not expect that any HAPs are present at or greater than 1.0 percent; and does not expect any carcinogenic HAPs to be present at or greater than 0.1 percent.
Directive 2011/65/EU (Restrictions of Hazardous Substances - RoHS), as amended by Commission Delegated Directive (EU) 2015/863 (RoHS 3)	The supplier does not routinely analyze the resin for the substances restricted by this regulation and does not expect these substances would be present above the specified limits: Lead (0.1 %); Mercury (0.1 %); Cadmium (0.01 %); 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 %).
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 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.
Directive 2006/122/EC (Relating to Restrictions on the Marketing and Use of Certain Dangerous Substances and Preparations (perfluorooctane Sulfonates), as amended	This directive is superseded by amendments to Regulation (EC) No. 1907/2006 Annex XVII (Restrictions on the Manufacture, placing on the market and use of certain dangerous substances, preparations and articles). Perfluorooctane sulfonates & salts & esters (PFOS) are listed with a restriction of <0.005%. The supplier does not analyze this resin for these substances. The supplier does not add these substances to the end product, and they do not expect that these substances will be formed during manufacturing or under normal handling, storage and use conditions. Based on the supplier's knowledge of their raw materials and manufacturing processes, they have no reason to expect that these substances would be present.
Regulation 2005/1895/EC (Epoxy Derivatives), as amended	This regulation replaced Directive 2002/16/EC and is applicable to plastics, surface coatings and adhesives. The following substances are prohibited: 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]; other Novolac glycidyl ethers (NOGE). These substances are not used in the manufacture of this product. The supplier does not conduct specific analysis for these substances.
Directive 2012/19/EU (to replace Directive 2002/96/EC) - Waste Electrical and Electronic Equipment (WEEE), as amended	The purpose of this directive, as a first priority, is the prevention of waste electrical and electronic equipment. In addition, it addresses the reuse, recycling and other forms of recovery of such wastes so as to reduce the disposal of waste. It also seeks to improve the environmental performance of all operators involved in the life cycle of electrical and electronic equipment, e.g. producers, distributors and consumers, and in particular those operators directly involved in the treatment of waste electrical and electronic equipment. The supplier has no reason to expect that this product as marketed would contain substances that will obstruct the reuse, recycling or other forms of recovery of the waste of electrical and electronic waste.
Health Canada – Inventory	None of the substances listed in the Canadian Chemicals Management Plan Challenge List Batches (Batches 1 through 12) are intentionally added to this resin according to the supplier. Based on the supplier's current knowledge of the raw materials and processes used in its manufacture, the supplier has no reason to expect that any of these substances would be present.

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Raw Material Number: 8-0001-32 (continued)

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 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. It would be the responsibility of the final user of the polymer to confirm levels in the final product as the results can be dependent on sample history and conversion conditions. (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	This product is supplied as polymer pellets and is not considered a drug substance nor excipient. The supplier does not routinely analyze their polymer products for the presence of the elements listed under the Guideline for Elemental Impurities ICH Q3D. However, if any were found to be present, the levels would be expected to be below the concentrations calculated from the established Permitted Daily Exposures in these guidelines.
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). The supplier has not specifically analyzed this product 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.
Directive 2003/53/EC (Restricting Nonylphenol and Nonylphenol Ethoxylates), as amended	The supplier does not analyze this product for nonylphenol and nonylphenol ethoxylates. Emulsifiers are not used as a raw material, nor are they added to the manufacturing process or the end product. Therefore, the supplier have no reason to expect that these substances are present.
EU Regulation 208/2005 on Polycyclic Aromatic Hydrocarbons (PAHs), as amended	Regulation (EC) No. 208/2005 and Regulation (EC) No. 466/2001 are obsolete. Regulation (EC) No. 1272/2013 amended Entry 50 of Annex XVII to REACH Regulation (EC) No. 1907/2006 on the restrictions of polycyclic aromatic hydrocarbons (PAHs). In addition, Regulation 2015/326/EU also amended Regulation (EC) No. 1907/2006. Following are the listed PAHs: Benzo[a]pyrene (BaP); Benzo[e]pyrene (BeP); Benzo[a]anthracene (BaA); Chrysene (CHR); Benzo[b]fluoranthene (BbFA); Benzo[j]fluoranthene (BjFA); Benzo[k]fluoranthene (BkFA); Dibenzo[a,h]anthracene (DBAha). 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 the listed substances would be present in this product.
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 (an organic substance with an initial boiling point less than or equal to 250 °C at a standard pressure of 101,3kPa).
Conflict Minerals	Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com
Pharmacopoeia	
US Pharmacopeia – Class VI	Samples made from this product were sterilized (Gamma at 50 kGy dosage and ETO at 130 degrees F), and these samples passed the following FDA-Modified ISO 10993 tests with human tissue contact time of 30 days or less: cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), implantation, hemocompatibility, physicochemical (USP).
US Pharmacopeia – USP Monograph	USP General Chapter < 661 > is "Plastic Packaging Systems And Their Materials Of Construction". Section 661.1 is titled "Plastic Materials Of Construction." It provides test methods and specifications for plastic materials of construction used in packaging systems. The following is stated: A plastic material of construction is deemed to be well-characterized for its intended use if the following characteristics have been adequately established: its identity, biocompatibility (biological reactivity), general physicochemical properties, and composition (i.e., additives and extractable metals likely to be present). A representative sample of this product met the requirements for the following physicochemical tests: heavy metals, nonvolatile residue, residue on ignition, and buffering capacity from water extracts. These tests are not routinely conducted on the product.

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Raw Material Number: 8-0001-32 (continued)**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.
Regulation 1169/2001, Annex II (Substances or products causing allergies or intolerances)	In regard to the presence of allergens and products which cause intolerances, this product is not manufactured with the following listed substances or products thereof: cereals containing gluten; crustaceans; eggs; fish; peanuts; soybeans, milk, nuts (almonds, hazelnuts, walnuts, cashews, pecans, Brazil nuts, pistachio nuts, macademia or Queensland nuts), celery, mustard, sesame seeds, sulphur dioxide and sulphites at concentrations of more than 10mg/kg or 10 mg/litre in terms of the total SO ₂ , lupin, and molluscs.

Other

GMO (Genetically Modified Organisms) Plant Origin	This product is not derived from plant sources and, therefore, is not produced using genetically modified organisms (GMOs) or recombinant DNA technology.
Directive 2001/18/EC and Regulations 1829/2003 and 1830/2003 (Genetically Modified Organisms), as amended	Based on the supplier's knowledge of the raw materials or based on supplier information, this product is considered not genetically modified or not derived from a genetically modified organism as defined in these regulations.
Kosher Certification	The supplier has not sought or received kosher certification for this product, nor does the supplier currently manufacture it under rabbinical supervision. However, the supplier does not use any animal-derived raw materials or additives in the production of this product. Accordingly, it is the supplier's understanding that the kosher status of foods packaged in containers made from this product, as supplied from their manufacturing sites, is not adversely affected by the use of this polymer.
Absence of Following Substances and Chemicals:	Bisphenols (BPA, BPF, BPS) Latex Melamine Natural rubber latex Nitrites Nitrosamine or Nitrocellulose or nitro-group or free amine Per- and Polyfluoroalkyl (PFAS/PFOA/PFOS) Phthalates (DINP, DEHP, DBP, DIDP, DNOP, DIBP, DPENP, DHEXP, DHCP) Polyvinyl chloride (PVC) 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.

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).

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

Clean Air Act (EC) 1005/2009	This product does not contain any of the following substances regulated by the Clean Air Act: • 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, Tl, 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.
European Pharmacopoeia	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."
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.
EU 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.

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

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)

The color concentrate contains one or more ingredients (tallow derived) that are derived from bovine or porcine tallow that is sourced from the USA, Canada, and/or Mexico. To protect against the transmission of spongiform encephalopathies, the 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.

US FDA, EU EMA/410/01
Rev 3, and/or ISO 22442-1:2020

The supplier's raw material 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 meet the conditions of the EMA/410/01 rev 3 (https://www.ema.europa.eu/en/documents/scientific-guideline/minimizing-risk-transmitting-animal-spongiform-encephalopathy-agents-human-veterinary-medicinal_en.pdf), FDA guidance on Medical Devices Containing Materials Derived from Animal Sources (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-devices-containing-materials-derived-animal-sources-except-vitro-diagnostic-devices>) and/or ISO 22442-1 Annex C.5 (<https://www.iso.org/obp/ui/#iso:std:iso:22442:-1:ed-3:v1:en>).

The ADM content of this concentrate is listed as approved for use in food contact applications under the US FDA Food Contact regulations in both the US and EU.

If present, identification
of animal and country of origin

The colorant contains one or more ingredients (tallow derived) that are derived from bovine or porcine that are sourced from the USA, Canada, and/or Mexico.

Food Contact

Commission Regulation EU
10/2011 (and amendments)

Every monomer, additive or colorant selected to formulate the above concentrate is listed in of or more of the following regulations: Commission Regulation (EU) No. 10/2011, as amended, or either Council of Europe's AP(89) I Resolution, the French Positive List for Plastic Materials, or the Swiss Ordinance List Annex 6, Part A or B. The supplier has not reviewed for specific migration limits (SMLs), dual use additives per Regulation (EC No 1333/2008, or any restrictions of use in food, the materials or final article, for the components used in the concentrate).

US FDA 21 CFR

The ingredients selected to formulate the color concentrate are either "generally recognized as safe" (GRAS), prior-sanctioned, acceptable for food contact applications based upon legal opinion and/or supplier certification, subject to an effective Food Contact Notification (FCN), subject to a Threshold of Regulation exemption under 21CFR170.39 (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): (Parts 174, 175, 176, 177, 178, 181, 182, 184, and 186). The supplier has not reviewed specific acceptable food types, conditions of use, or any limitations or restrictions of use for the components used in the concentrate.

Applicable Regulations

Coalition of Northeastern
Governors (CONEG) and TPCH

Based on the documentation, the color concentrate was not formulated to contain lead, cadmium, mercury or hexavalent chromium above the allowable level of 100ppm total. In addition, these four elements are not intentionally added during the manufacturing process.

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.

Continued next page

Raw Material Number: 8-0097-17 (continued)

Toxic Substances Control Act (TSCA) section 6(h)	This colorant was not intentionally 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 2) - Directive 2011/65/EU, Annex II, as amended by Commission Delegated Directive 2015/863/EU (RoHS 3)	As formulated, this product does not contain any substances regulated under EU RoHS Directive (2011/65/EU) (RoHS 2, as amended by 2015/863; RoHS3) and China RoHS 2 (GB/T 26572) above threshold levels.
REACH EC/1907/2006 and Substances of Very High Concern (SVHC), and Annex 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 or substances from the Annex lists above 0.1% in the product. Nor have any of these substances been intentionally added during the manufacture of the product.
2011/65/EU (RoHS) 2002/96/EC, and 2012/19/EU (WEEE)	Since the colorant complies with the EU "Restriction of Hazardous Substances" (RoHS) Directive (2011/65/EU) and does not contain any of the RoHS listed materials, the color concentrate also complies with the WEEE Directive 2002/96/EC and 2012/19/EU. This declaration is based on formulation and supplier information, not based on testing.
94/62/EC, 2005/20/EC, and 2013/2/EU (Packaging Waste Directive)	Based on the reviewed documentation, the above listed concentrates were not formulated to contain lead, cadmium, mercury or hexavalent chromium above the allowable level of 100ppm total. Therefore, the amber colorant complies with the Packaging Waste Directive 94/62/EC, 2005/20/EC, and 2013/2/EU. This declaration is based on formulation and supplier information, not based on testing.
Conflict Minerals	Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com
ICH Guideline Q3C(R6) for Residual Solvents	The documentation for the raw materials used to formulate this color concentrate has been reviewed for any indication of the presence of the substance(s) noted. However, there was no indication found that the substance(s) are present in the raw materials. In addition, this color concentrate was not formulated to contain any of the noted substance(s) and the substance(s) are not intentionally introduced during the manufacture of this concentrate.
ICH Guideline Q3D on Elemental Impurities	The documentation for the raw materials used to formulate the color concentrate has not been analyzed for the presence of elemental impurities referenced in the International Conference on Harmonisation's ICH Q3D Guideline for Elemental Impurities. The supplier of the color concentrate is not required to comply with guidelines set by the International Conference on Harmonisation's ICH Q3D Guideline for Elemental Impurities. The ICH Q3D guidelines require the manufacturers of finished products to comply with the guidelines.
Allergen Information	
Consumer Protection Act of 2004	The color concentrate has 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 allergen, soybean oil, was found.

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Raw Material Number: 8-0097-17 (continued)	
Other	
Genetically Modified Organisms (GMO)	Based on supplier information Genetically Modified Organisms (GMOs) are present in the raw material.
Presence of Following Substances:	Plant Derived Material
Absence of Following Substances and Chemicals:	Bisphenol A (BPA) Bisphenol S (BPS) Latex/Natural rubber Melamine Nitrosamines or Nitrosating agents Ortho phthalates PFOA/PFOS/PFAS Phthalates Polyvinyl chloride (PVC)

Raw Material Number: 8-0099-33**Raw Material Description:**
Amber Colorant used in
PETG bottles 322021-XXXX and Serum vials 342033-0010

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 (EC) No 999/2001

The supplier states that its colorant does not intentionally contain ingredient materials that are animal or human derived. Therefore, the colorant would not be a potential source of Bovine Spongiform Encephalopathy (BSE)/ Transmissible Spongiform Encephalopathy (TSE).

Food ContactCommission Regulation EU
10/2011 (and amendments)

Not certified

US FDA 21 CFR

Not certified

Applicable RegulationsConsumer Product Safety
Improvement Act (CPSIA) of 2008

Based on the information provided to our supplier by its raw material suppliers and review of their product formula and processes, the colorant meets all requirements of the Consumer Product Safety Improvement Act of 2008.

Coalition of Northeastern
Governors (CONEG) and TPCB

The supplier states that the product does comply with current CONEG legislation. Based on the information provided to the supplier by its raw material suppliers and their formulation reviews, the colorant contains no known residuals of lead, mercury, cadmium or hexavalent chromium. Further, lead, mercury, cadmium and hexavalent chromium have not been intentionally introduced as an element during the manufacturing or distribution of this product or its packaging, at or above restricted concentrations (100 ppm). Note that the supplier does not routinely test for these materials.

California Proposition 65

The supplier has assessed this colorant based on the current list published by the Office of Environmental Health Hazard Assessment (OEHA://oehha.ca.gov/proposition-65). The supplier's evaluation has shown that no exposure warning is required for this colorant.

Substances that Deplete
the Ozone Layer

The supplier certifies the colorant identified above does not intentionally contain any chloro-fluoro carbon compounds or any other identified ozone-depleting ingredient materials.

EC Directive Recast 2011/65/
EU (ROHS 2) and (EU) 2015/863
(ROHS 3) on the Restriction of
the Use of Certain Hazardous
Substances (ROHS) and WEEE

Based on the information provided to the colorant supplier by their suppliers, the colorant does not contain any of the heavy metals (cadmium 0.01%, hexavalent chromium 0.1%, lead 0.1% and mercury 0.1%) or brominated fire retardants (commonly referred to as PBDEs), including decabromodiphenyl ether, regulated by this directive. The supplier does not routinely test for these materials. The supplier certifies that they do not intentionally add or use these materials in the manufacture or handling of the product, at or above restricted concentrations. Additionally, based on the information provided to the colorant supplier by their suppliers and review of the colorant formula and processes, they find that the formula for this colorant does not intentionally include phthalate ingredient materials, but they do not routinely test for phthalates.

REACH EC/1907/2006 Substances
of Very High Concern (SVHC),
Annexes XIV and XVII

The supplier confirms that the colorant 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 colorant or substances from the Annex lists. Nor have any of these substances been intentionally added during the manufacture of the colorant.

Toxic Substances Control Act
(TSCA)

This colorant was not intentionally 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).

EC 1895/2005 (BADGE, BFDGE,
NOGE)

Based on the information provided to the colorant supplier by its raw material suppliers and their formulation review, they found that this colorant does not intentionally contain BPA, BPF, BPS, BADGE, BFDGE or NOGE substances. Please note the supplier does not routinely test for BPA, BPF, BPS, BADGE, BFDGE or NOGE. The supplier certifies that they do not intentionally add or use BPA, BPF, BPS, BADGE, BFDGE or NOGE in the manufacture or handling of this colorant.

Continued next page

Raw Material Number: 8-0099-33 (continued)

ICH Guideline Q3C(R6) for Residual Solvents	Based on the information provided to the supplier by its raw material suppliers and review of the product formula and processes, the supplier does not intentionally include Class 1, 2, or 3 solvents listed in the ICH Q3C Table and List Guidance for Industry. Please note that the supplier does not routinely test for these residual solvents. The supplier certifies that they do not intentionally add or use these solvents in the manufacturing or handling of this product.
ICH Guideline Q3D on Elemental Impurities	The supplier of the colorant states that based on the information provided to them by their suppliers and to the best of their knowledge, the formula for this product does not intentionally include any of the Class 1, 2A, 2B or 3 elemental impurities as referenced in ICH Q3D Guidelines of Elemental Impurities (Rev. Dec. 2014). Please note that this product has not been subjected to testing in order to definitively identify the presence of these substances. The supplier certifies that they do not intentionally add or use these substances in the manufacturing or handling of 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	Based on the information provided to our supplier by its raw material suppliers and review of the colorant formula and processes, the colorant does not intentionally contain peanuts, tree nuts, milk, eggs, wheat gluten, soybeans, fish, and shellfish, any of these substances identified as food allergens or derivatives of these food allergens. Please note that they do not routinely test for allergens. Also note that the facilities which manufacture this colorant may use epoxidized soybean oils (ESO), which are refined, deodorized, and bleached, but are a derivative of soybean.
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Other

Genetically Modified Organisms (GMO)	Based on information provided to the colorant supplier by its raw material suppliers and review of the product formula and processes, the supplier does not intentionally include any genetically modified organism ingredient materials. Please note that the supplier does not routinely test for these materials. The supplier certifies that they do not intentionally add or use GMO's in the manufacturing or handling of this product.
Presence of Following Substances and Chemicals:	Plant derivatives
Absence of Following Substances and Chemicals:	Bisphenol A (BPA) Bisphenol S (BPS) Dry natural rubber Latex (or derived ingredients) Melamine Natural rubber latex Nitrosamines Phthalates Polyvinyl chloride (PVC) Silicone

Raw Material Number: 8-0099-34**Raw Material Description:
White Colorant for bottles and 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)

The color concentrate contains one or more ingredients (tallow derived) that are derived from bovine or porcine tallow that is sourced from the USA, Canada, and/or Mexico. To protect against the transmission of spongiform encephalopathies, the 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.

US FDA, EU EMA/410/01 Rev 3,
and/or ISO 22442-1:2020

The supplier's raw material 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 meet the conditions of the EMA/410/01 rev 3 (https://www.ema.europa.eu/en/documents/scientific-guideline/minimizing-risk-transmitting-animal-spongiform-encephalopathy-agents-human-veterinary-medicinal_en.pdf), FDA guidance on Medical Devices Containing Materials Derived from Animal Sources (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-devices-containing-materials-derived-animal-sources-except-vitro-diagnostic-devices>) and/or ISO 22442-1 Annex C.5 (<https://www.iso.org/obp/ui/#iso:std:iso:22442:-1:ed-3:v1:en>).

The ADM content of this concentrate is listed as approved for use in food contact applications under the US FDA Food Contact regulations in both the US and EU.

Food Contact

The raw materials selected to formulate the color concentrate, meet the relevant requirements of the following regulations:

- Regulation (EC) No. 1935/2004 known as the Framework regulation, as amended
- Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food, as amended
- Commission Regulation (EU) No. 10/2011, as amended or the Council of Europe's AP(89) I Resolution, the French Positive List for Plastic Materials, or in the Swiss Ordinance List Annex 6, Part A or B.

Commission Regulation EU
10/2011 (and amendments)

The concentrate contains one or more monomers and/or additive(s) that are regulated with a specific migration limit and one or more dual use additives per Regulation (EC) No 1333/2008 or as flavorings by Regulation (EC) No 1334/2008.

US FDA 21 CFR

The ingredients the supplier selected to formulate the 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): Parts 174, 175, 176, 177, 178, 181, 182, 184 and 186. The supplier has not reviewed specific acceptable food types, conditions of use, or any limitations or restrictions of use for the components used in the color concentrate.

Applicable Regulations

Coalition of Northeastern
Governors (CONEG and TPCH)

Based on the documentation, the colorant was not formulated to contain lead, cadmium, mercury or hexavalent chromium above the allowable level of 100 ppm total. In addition, the four elements are not intentionally added during the manufacturing process.

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Raw Material Number: 8-0099-34 (continued)

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.
Restriction of Hazardous Substances (RoHS 3) - Directive 2015/863/EU which amends Annex II of 2011/65/EU and China RoHS 2	As formulated, this colorant does not contain any substances regulated under EU RoHS Directive (2011/65/EU) (RoHS 2, as amended by 2015/863; RoHS 3) and China RoHS 2 (GB/T 26572) above threshold levels.
REACH EC/1907/2006 and Substances of Very High Concern (SVHC)	Based on formulation and supplier information, the concentrate was not formulated to contain any 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 colorant or substances from the Annex lists. Nor have any of these substances been intentionally added during the manufacture of the colorant.
2002/96/EC, and 2012/19/EU (WEEE)	The colorant complies with the WEEE Directive 2002/96/EC and 2012/19/EU. This declaration is based on formulation and supplier information, not based on testing.
Directive 94/62/EC, Packaging & Packaging Waste (amended by 2004/12/EC, 2005/20/EC, and Regulation (EC) No. 219/2009)	The colorant was not formulated to contain lead, cadmium, mercury or hexavalent chromium above the allowable level of 100 ppm total. Therefore, the colorant complies with the Packaging Waste Directive 94/62/EC, 2005/20/EC, and 2013/2/EU. This declaration is based on formulation and supplier information, not based on testing.
ICH Guideline Q3C(R6) for Residual Solvents	There are no indication residual solvents under ICH Q3C(R6) Guidelines are present in the raw materials. In addition, this colorant was not formulated to contain any of the noted substance(s) and the substance(s) are not intentionally introduced during the manufacture of this colorant.
ICH Guideline Q3D on Elemental Impurities	The documentation for the raw materials used to formulate the colorant has not been analyzed for the presence of elemental impurities referenced in the International Conference on Harmonisation's ICH Q3D Guideline for Elemental Impurities.
Conflict Minerals	Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com

Allergen Information

Consumer Protection Act of 2004	The colorant has been reviewed for any indication that the eight major substances considered allergens per the <i>Food Allergen Labeling and Consumer Protection Act of 2004</i> (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.
EU Regulation No. 1169/2011	The colorant has been reviewed for any indication that Allergens (according to the EU Regulation No. 1169/2011) are present in the raw materials. There was no indication that any substances were found.

Other

Genetically Modified Organisms (GMO)	Genetically Modified Organisms (GMO) are present in the raw materials used to formulate this product.
Presence of Following Substances and Chemicals:	Calcium carbonate Plant Derived Material
Absence of Following Substances and Chemicals:	Bisphenol A (BPA) Bisphenol-S (BPS) Latex Melamine Nitrites, Nitrocellulose, Nitrosamines, Nitro/Nitroso groups PFOA / PFOS / PFAS Phthalates, Ortho-phthalates Silicone Persistent, Bioaccumulative, and Toxic (PBT chemicals)

Raw Material Number: 8-0099-43**Raw Material Description:
Black Colorant**

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 (EC) No 999/2001

The raw materials used to formulate the color concentrate have been reviewed for any indication of the presence of Animal Derived Materials (ADM). There was no indication that ADM substances are present in this concentrate. ADM substances were not intentionally added during the manufacture of this concentrate. This declaration is based on formulation and supplier information, not based on testing. It does not exclude the presence of traces due to impurities or residuals in the components supplied by third parties and used in the supplier's production facilities.

Food ContactCommission Regulation EU
10/2011 (and amendments)

The raw materials selected to formulate the color concentrate meet the relevant requirements of Regulation (EC) No. 1935/2004 known as the Framework Regulation and Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as amended. Every monomer and additive selected to formulate the color concentrate are listed in the Commission Regulation (EU) No. 10/2011, as amended. This concentrate contains one or more monomers and/or additive(s) that are regulated with a specific migration limit. In the production of this concentrate, no migrating 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 are intentionally used. This declaration is based on formulation and supplier information, not based on testing. It does not exclude the presence of traces due to impurities or residuals in the components supplied by third parties and used in the supplier's production facilities.

US FDA 21 CFR

The ingredients selected to formulate the color concentrate are either "generally recognized as safe" (GRAS), prior-sanctioned, subject to an effective Food Contact Notification (FCN), or a Threshold of Regulation exemption (TOR) under 21CFR170.39, 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): 174, 175, 176, 177, 178, 181, 182, 184, and 186.

Applicable RegulationsCoalition of Northeastern
Governors (CONEG) and TPCB

Based on documentation, the color concentrate is not formulated to contain lead, cadmium, mercury or hexavalent chromium above the allowable level of 100ppm total. In addition, these four elements are not intentionally added during the manufacturing process.

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.

Directive 2011/65/EU, Annex II
Restriction of Hazardous
Substances (RoHS 2) - as amended
by Commission Delegated Directive
2015/863/EU (RoHS 3) and China
RoHS 2 (GB/T 26572)

As formulated, this color concentrate does not contain any substances regulated under EU RoHS Directive (2011/65/EU) (RoHS 2, as amended by 2015/863; RoHS 3) and China RoHS 2 (GB/T 26572) above threshold levels.

REACH EC/1907/2006 Substances
of Very High Concern (SVHC),
Annex XIV and XVII

The supplier confirms that the color concentrate 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 color concentrate or substances from the Annex lists. Nor have any of these substances been intentionally added during the manufacture of the color concentrate.

Continued next page

Raw Material Number: 8-0099-34 (continued)

2011/65/EU, 2002/96/EC, and 2012/19/EU (WEEE)	Based on compliance with the EU "Restriction of Hazardous Substances" (RoHS) Directive 2011/65/EU, the color concentrate does not contain any of the RoHS listed materials. The color concentrate also complies with the WEEE Directive 2002/96/EC and 2012/19/EU. The color concentrate is not formulated to contain lead, cadmium, mercury or hexavalent chromium above the allowable level of 100 ppm total. This declaration is based on formulation and supplier information, not based on testing.
94/62/EC, 2005/20/EC, and 2013/2/EU (Packaging Waste Directive)	Based on the reviewed documentation, the color concentrate is not formulated to contain lead, cadmium, mercury or hexavalent chromium above the allowable level of 100ppm total. Therefore, the color concentrate complies with the Packaging Waste Directive 94/62/EC, 2005/20/EC, and 2013/2/EU. This declaration is based on formulation and supplier information, not based on testing.
ICH Guideline Q3D on Elemental Impurities	The documentation for the raw materials used to formulate the color concentrate has not been analyzed for the presence of elemental impurities referenced in the International Conference on Harmonisation's ICH Q3D Guideline for Elemental Impurities. The supplier of the color concentrate is not required to comply with guidelines set by the International Conference on Harmonisation's ICH Q3D Guideline for Elemental Impurities. The ICH Q3D guidelines require the manufacturers of finished products to comply with the guidelines.
Conflict Minerals	Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com

Allergen Information

Consumer Protection Act of 2004	The raw materials used to formulate the color concentrate have been reviewed for the presence of (FALCPA) Allergens; Milk, egg, peanuts, tree nuts, wheat gluten, soybeans, fish and shellfish are not present in the raw materials above 1000 ppm. The color concentrate is not formulated to contain these substances, nor are they intentionally added during the manufacture of the color concentrate.
Presence of Following Substances and Chemicals	Vinyl Acetate 2,6-di-tert-butyl-p-cresol Acrylic Acid Genetically Modified Organisms (GMOs) Plant Derived Material
Absence of Following Substances and Chemicals	Bisphenol A (BPA) Bisphenol S (BPS) Latex Melamine Nitrosamines Ortho-phthalates PFOS/PFOA/PFAS Phthalates Polyvinyl chloride (PVC) Silicone TSCA – (PBT chemicals)

 Learn more at thermofisher.com/mediabottles

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