



Nalgene HDPE bottles with closure

Product regulatory guide

Contents

	How to use this guide	1
Section 1	Materials of construction	2
Section 2	Key product specifications	4
Section 3	Material information sheets	7
	Raw material number: 8-0029-04	7
	Raw material number: 8-0042-01	10
	Raw material number: 8-0042-31	13
	Raw material number: 8-0049-06	16
	Raw material number: 8-0071-06	19
	Raw material number: 8-0099-06	21
	Raw material number: 8-0099-34	23
	Raw material number: 8-0099-74	25
	Raw material number: 8-0099-75	27

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™ HDPE bottles with closure. 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

Nalgene Product Families	Material Information	
	Component Part Number	Description
2002-XXXX		
2007-XXXX		
2018-XXXX		
2089-XXXX		
2097-XXXX		
2099-XXXX		
2104-XXXX		
2114-XXXX		
2189-XXXX		
2197-XXXX		
2199-XXXX		
3121-XXXX		
312002-XXXX	8-0042-31	High Density Polyethylene (HDPE) Bottle Resin
312007-XXXX	8-0071-06	Polypropylene (PP) Closure Resin
312018-XXXX		
312089-XXXX		
312097-XXXX		
312099-XXXX		
312104-XXXX		
312114-XXXX		
312189-XXXX		
312199-XXXX		
322002-XXXX		
322089-XXXX		
332089-XXXX		
332189-XXXX		
382099-XXXX		
362008-XXXX	8-0042-31 8-0099-34	High Density Polyethylene (HDPE) Bottle Resin White Colorant
362002-XXXX 362089-XXXX	8-0042-31	High Density Polyethylene (HDPE) Bottle Resin

Continued next page

Nalgene Product Families	Material Information (continued)	
	Component Part Number	Description
2120-XXXX		
2123-XXXX		
2124-XXXX		
2125-XXXX		
2211-XXXX	8-0042-31	High Density Polyethylene (HDPE) Bottle Resin
2241-XXXX	8-0071-06	Polypropylene (PP) Closure Resin
2303-XXXX	8-0099-34	White Colorant
342002-XXXX		
342089-XXXX		
342289-XXXX		
2240-XXXX	8-0042-31	High Density Polyethylene (HDPE) Bottle Resin
2242-XXXX	8-0071-06	Polypropylene (PP) Closure Resin
2243-0013	8-0099-34	White Colorant
	8-0042-01	High Density Polyethylene (HDPE) Closure Resin
2243-9013	8-0042-31	High Density Polyethylene (HDPE) Bottle Resin
	8-0071-06	Polypropylene (PP) Closure Resin
	8-0099-34	White Colorant
	8-0042-01	High Density Polyethylene (HDPE) Closure Resin
	8-0029-04	Polypropylene (PP) Closure Strap Resin
	8-0099-74	Blue Colorant
	8-0049-06	Linear Low-Density Polyethylene (LLDPE) Resin
	8-0099-74	
2214-XXXX	8-0042-31	High Density Polyethylene (HDPE) Bottle Resin
	8-0099-06	High Density Polyethylene (HDPE) UV Additive
	8-0042-01	High Density Polyethylene (HDPE) Closure Resin
2242-XXXX	8-0042-31	High Density Polyethylene (HDPE) Bottle Resin
	8-0071-06	Polypropylene (PP) Closure Resin
	8-0099-34	White Colorant
	8-0042-01	High Density Polyethylene (HDPE) Closure Resin
2320-XXXX	8-0042-31	High Density Polyethylene (HDPE) Bottle Resin
	8-0071-06	Polypropylene (PP) Closure Resin
	8-0099-34	White Colorant
	8-0042-01	High Density Polyethylene (HDPE) Closure Resin
	8-0071-06	Polypropylene (PP) Closure Resin
	8-0099-74	Blue Colorant
2421-XXXX	8-0042-31	High Density Polyethylene (HDPE) Bottle Resin
	8-0071-06	Polypropylene (PP) Closure Resin
	8-0099-75	Red Colorant

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

Manufacturing Locations*			Product Release Location
Thermo Fisher Scientific Monterrey (Plant B), Ave Miguel Alemán km21, Edificio 3 Parque Prologis Apodaca, Apodaca, Nuevo León, México 66600	Nalge Nunc International Corporation, A part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive Rochester, NY 14625	Nalge Nunc International Corporation, A part of Thermo Fisher Scientific Inc. 236 Perinton Parkway Fairport, NY 14450	Nalge Nunc International Corporation, A part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive Rochester, NY 14625

*Products are manufactured at one of these three manufacturing locations.

Contact Technical Support at +1-800-625-4327 or technicalsupport@thermofisher.com with any questions.

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.
Performance Inspection (Leak Testing)	Performance inspection is performed on product samples collected at regular intervals throughout each production run.
Passive Leak Tested for 15 minutes	2120-XXXX, 2123-0010, 2211-XXXX, 2303-0050, and 2320-XXXX PLUS 2 psi for 2 min on closure and 5 psi for 2 min on spigot
Vacuum Leak Test at 2.5 psi for 2 minutes	312002-9125, 322002-9125, 362002-9125, 362008 -9125

Continued next page

Manufacturers (continued)

Leak Tested at 2 psi for 2 minutes	2002-XXXX
	2007-XXXX
	2018-XXXX
	2089-XXXX
	2104-XXXX
	2114-XXXX
	2125-XXXX
	2189-XXXX
	2214-XXXX
	2240-XXXX
	2243-XXXX
	3121-XXXX
	312104-XXXX
	312189-XXXX
	312007-XXXX
	312018-XXXX
	312089-XXXX
	322089-XXXX
	332189-XXXX
	312002-XXXX, except -9125
	322002-XXXX, except -9125
	362002-XXXX, except -9125
	362008-XXXX, except -9125
	2002-XXXX, except 7 psig for 2 minutes on 2002-9016
Leak Tested at 10 psi for 2 minutes	2099-0004, 2099-0010, 2199-XXXX, 312099-XXXX, 312199-XXXX, 382099-XXXX
Leak Test starting at 3.6 psig and increase at a rate of 3.6 psig per minute until reach 15 psig, hold for 30 minutes	2099-0001, 2099-0002, 2099-0008, 2099-0016, 2099-0032
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>.
Additional Product Information	
Sterilization (Sterile SKUs only)	Irradiated at 19–28 kGy
	342002-XXXX 342089-00XX
	Irradiated at 25–40 kGy 342289-00XX
	Product is Gamma Irradiation Sterilized. Sterility assurance level (SAL): 10 ⁻⁶ where product has a shelf life. Product was dosimetric released per ANSI/AAMI/ISO 11137 guidelines.

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Manufacturers (continued)

Certifications

- The materials listed in Table 1 have been tested for compliance to the following:
- Non-Cytotoxic – tested per USP <87> Elution Test, Biological Reactivity Tests, In Vitro or ISO 10993-5*
 - Exclusions – 8-0049-06 and 8-0099-06
 - USP Class VI Plastic – tested per USP <88>, Biological Reactivity Tests, In Vivo*
 - Exclusions – 8-0049-06 and 8-0099-06
- * For test method details, contact ROCRegSupport@ThermoFisher.com

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Material information sheets

Raw Material Number: 8-0029-04

Raw Material Description: Polypropylene Copolymer (PPCO) 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 supplier confirms the components derived from animal sources are not used in the manufacture or formulation of this product. One or more additives in this product may be derived from vegetable sources.
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Food Contact

Commission Regulation EU 10/2011 (and amendments)	This product complies with the requirements of Regulation 10/2011/EC (PIM) as amended, applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes). The monomers and additives used to produce this product are listed in Union List of Authorized Substances of Regulation 10/2011/EC and subsequent amendments. EU Regulation 10/2011/EC specifies 10mg/dm ² as the maximum overall migration (OML) from the finished plastic food contact material or article. The OML and SMLs (when applicable) should be determined according to the requirements specified in EU Regulation 10/2011/EC and subsequent amendments. The manufacturers of the finished food contact material or article must verify that the finished material or article, manufactured according to good manufacturing practices, does not modify the organoleptic properties of the food.
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US FDA 21 CFR	This product meets the FDA requirements outlined in the Code of Federal Regulations 21 CFR 177.1520(a)(3)(i) and (c)3.2a. This product may also contain adjuvant substances that may be safely used in polymers used for the manufacture of articles that come into direct contact with food. According to the supplier's information, the substances used in the product meet FDA regulations and 21 CFR 177.1520(b). This product meets the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21 CFR 176.170(c), Table 2, and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1.
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China - National Food Safety Standards on GB4806.1-2016, GB4806.6-2016, and GB9685-2016	This product complies with requirements of GB4806.1-2016 – Food Contact Material & Articles General Safety Requirement, as applicable to Plastic Resins. The base resin in this product complies with the specifications established in GB4806.6-2016, “National Food Safety Standard: Food Contact Resins”, Appendix A.1, Serial Number 29, resin type PP.” No monomer(s) with SMLs are present in this base resin. The additives used in this product comply with the requirement of “GB9685-2016 National Food Safety Standard: Additives for use in Food Contact Materials and Articles” and relevant approval announcements. Additives with Max Residual (QM) are not intentionally used in this product.
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Raw Material Number: 8-0029-04 (continued)**Applicable Regulations**

Coalition of Northeastern Governors (CONEG and TPCH)	Based on the available documentation provided by the raw material suppliers, this product complies with the CONEG Model Legislation for requirements regarding the defined limit for the sum of heavy metals (lead, mercury, cadmium, and hexavalent chromium).
California Proposition 65	This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or other reproductive harm as of the current Proposition 65 list.
Clean Air Act Amendments of 1990	Materials listed in the Clean Air Act Amendments of 1990 (Class I, CFC's and Class II HCFC's, Halons and the solvents, carbon tetrachloride and 1,1,1-trichloroethane) are not intentionally used in the production of this product.
Restriction of Hazardous Substances (RoHS 3) - Directive 2015/863, 2002/95/EC, and 2011/65/EU, as amended	Based on the available documentation from raw materials suppliers, this product complies with the requirements of the Directives EU 2015/863, 2002/95/EC and 2011/65/EU, as amended, concerning the limits of cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), and diisobutyl phthalate (DIBP).
China RoHS – Regulation GB/T 26572-2011	Based on the available documentation from raw materials suppliers, this product complies with the requirements of the GB/T 26572-2011 “Restricted Substances in Electronic and Electrical Products” concerning the limits of cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB), and polybrominated diphenyl ethers (PBDE).
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 into contact with foodstuffs as plasticizers, additives or raw materials.
EU National Legislations Regulations, Germany: BfR Recommendation VII and Warenwet: Verpakkingen en Gebruiksartikelen - Kunststoffen	The composition of this product complies with the National Legislations, Recommendations or Communications for the production of food packaging.
94/62/EC and as amended (Packaging Waste Directive)	Based on the available documentation from the raw material supplier, this product complies with the Directive 94/62/EC and as amended concerning the defined limit(s) of heavy metals.
Toxic Substances Control Act (TSCA)	This product was not formulated to contain decabromodiphenyl ether (DecaBDE), phenol, isopropylated phosphate (3:1) (PIP (3:1)), 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP), hexachlorobutadiene (HCBd), or pentachlorothiophenol (PCTP).
REACH EC/1907/2006 and Substances of Very High Concern (SVHC), Annex XIV	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 XIV authorization lists above 0.1% in the product. Nor have any of these substances been intentionally added during the manufacture of the product.
Conflict Minerals	Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com

Allergen Information

Consumer Protection Act of 2004 (FALCPA)	No major food allergens, such as Milk, Eggs, Fish, Crustacean Shellfish, Tree Nuts, Wheat, Peanuts, Soybeans, Sesame Seeds, and Sulphites; nor protein derived from them are used in the formulation or manufacture of this product. This product has not been tested for these substances.
European Regulation 1169/2011	The food ingredients listed in Annex II of Regulation (EU) No. 1169/2011, are not used in the manufacture of or formulation of this product. This product has not been tested for these substances.

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Raw Material Number: 8-0029-04 (continued)**Other**

Genetically Modified Organisms (GMO) Plant Origin	Components derived from vegetable sources are used in the manufacture of this product. These vegetable sources are not believed to be sourced from Genetically Modified Organisms (GMO's).
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Kosher Certification	This product is not certified Kosher.
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Halal Certification	The supplier does not certify the resin to be Halal or in compliance with Halal requirements.
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Presence of Following Substances and Chemicals:	Aluminum substances Octadecyl 3-(4-hydroxy-3,5-di-tert-butylphenyl)propionate Propanoic acid, 3,3'-thiobis-, dioctadecyl ester
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Absence of Following Substances and Chemicals:	Bisphenols A, B, C, E, F, G, M, P, S, T and Z Latex Melamine (1,3,5-Triazine-2,4,6-triamine) Nitrosamines Perfluoroalkylated and Polyfluoroalkylated Substances; PFASs Perfluorooctane Sulfonate (PFOS) Perfluorooctanoic acid (PFOA) Phthalates Polyvinyl chloride; (PVC) Silicone
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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 TPCP

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 (HCBT); and Pentachlorothiophenol (PCTP).

Continued next page

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

Clean Air Act (EC) 1005/2009	<p>This product does not contain any of the following substances regulated by the Clean Air Act:</p> <ul style="list-style-type: none">• Class I or Class II Ozone-Depleting Substances (CAA Section 602)• Hazardous Air Pollutants (CAA Section 112)• Accidental Release Prevention Substances (CAA Section 112(r))• Volatile Organic Chemicals (CAA Section 111)
Restriction of Hazardous Substances (RoHS 3) - Directive 2015/863/EU, 2011/65/EU and 2002/95/EC	No heavy metals (i.e., antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium, or silver) are purposely added to this product in quantities that would violate governmental guidelines. The summation of lead, cadmium, mercury, and hexavalent chromium in this product is less than 20 ppm. No polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), Deca Brominated Diphenyl Ethers (Deca BDE), or phthalates are intentionally added to this product. This product therefore meets the relevant requirements of the 2015/863/EU, 2011/65/EU and 2002/95/EC (RoHS) Directives and Regulations.
2002/96/EC and 2012/19/EU (WEEE)	This product meets the relevant requirements of this directive.
2000/53/EC (ELV)	This product meets the relevant requirements of this guidance document.
94/62/EC, 2005/20/EC, and 2013/2/EU (Packaging Waste Directive)	This product meets the relevant requirements of this directive.
REACH EC/1907/2006 and Substances of Very High Concern (SVHC) and Annexes XIV and XVII	The supplier confirms that the product does not contain any of the substances included on the current Candidate List of Substances of Very High Concern (SVHC) under REACH. This product does not contain substances restricted under REACH Annex XVII (Restricted Substances List) or subject to authorization under REACH Annex XIV (Authorization List).
ICH Guideline Q3D on Elemental Impurities	The resin supplier states that the product does not intentionally contain the metals described in the ICH Harmonized Guideline for Elemental Impurities Q3D dated March 22 2019 (including Cd, Pb, As, Hg, Co, V, Ni, Ti, Au, Pd, Ir, Os, Rh, Ru, Se, Ag, Pt, Li, Sb, Ba, Mo, Cu, Sn, Cr).
EU Directives 2002/16/EC and 1895/2005	The resin supplier states that the resin does not contain Epoxy derivatives listed in the EU Directives 2002/16/EC and 1895/2005.
Conflict Minerals	Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com
Pharmacopoeia	
Pharmacopoeia USP 39 <87>	This product meets the standards set by the United States Pharmacopoeia USP 39 <87> Biological Reactivity Tests, in Vitro.
Pharmacopoeia USP 26 <88>	This product meets the standards set by the United States Pharmacopoeia USP 26 <88> Biological Reactivity Tests, in Vivo- Class VI Plastics - 70oC.
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	Europe 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.” an Pharmacopoeia
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.

Continued next page

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

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Substances of Animal Origin (BSE/TSE)

Regulation 999/2001

The supplier does not deliberately add any animal-derived substances (including bovine or tallow-derived substances), kosher/halal-offending constituent substances, or any animal substances that may carry the risk of transmitting Bovine Spongiform Encephalopathy (BSE) or transmissible Spongiform Encephalopathy (TSE), nor are such substances present, to the best of the supplier's knowledge, in any of the raw materials used in the product's manufacture. The raw materials used in the manufacture of the product contain no animal by-products.

Food Contact

Commission Regulation EU 10/2011 (and amendments)

The product complies with the European Union's food contact regulations including the Framework Regulation (EC) No. 1935/2004, Regulation (EC) No. 2023/2006 (GMP) and Regulation (EU) No. 10/2011, as amended, Annex I (including Table 1, Union list of authorized substances) and Annex II. In addition, the resin complies with the relevant national regulations of the EU member states and non-EU countries which have adopted the European Union legislation. None of the product's components are subject to Specific Migration Limits (SML) or other restrictions as listed in the above mentioned annexes I and II. In addition, the resin does not contain any intentionally introduced dual-use additives.

US FDA 21 CFR

The product complies with the provisions of the United States Federal Food, Drug, and Cosmetic Act which are applicable to the product, and all applicable Food and Drug Administration (FDA) regulations. Specifically, the product complies with the specifications contained in the FDA regulation 21 CFR 177.1520 for olefin polymers, para. (c) 3.2a and may thus be used in the United States as an article or component of an article intended for use in contact with food, without food-type restrictions, under Conditions of Use A-H (21 CFR 176.170 (c) Table 2).

Canadian Health Products and Food Branch (HPFB) Status

HPFB has no objection to the use in Canada of the product in food contact applications for which the product is technically suitable.

Applicable Regulations

Coalition of Northeastern Governors (CONEG)

The supplier does not deliberately add cadmium, hexavalent chromium, lead or mercury to the product. The supplier has carried out testing on representative grades and the above heavy metals were not detected. The product as supplied does not contain the above heavy metals at concentrations of 100 ppm (total) or above, thus satisfying the requirements of the CONEG and TPCH Model Toxics in Packaging Legislation, the California Toxics in Packaging Prevention Act (California Health and Safety Code, §25214.11-25214.21), and EU Directive 94/62/EC Packaging Regulations for heavy metals, as amended.

California Proposition 65

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

Toxic Substances Control Act (TSCA)

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

Substances that deplete the Ozone layer (Montreal Protocol)

The product, as supplied, does not contain and is not manufactured with Class I or Class II ozone-depleting chemicals. Thus, the product will not require labeling under 40 CFR 82, subpart E (U.S. Stratospheric Ozone Protection Regulations, Labeling of Products using Ozone-Depleting Substances). In addition, the product does not contain, and is not manufactured with, any atmospheric ozone layer-depleting chemicals cited in the Montreal Protocol of 1987, as amended.

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Raw Material Number: 8-0042-31 (continued)

Restriction of Hazardous Substances (RoHS) - (EU) Directive 2015/863 which amends Annex II of 2011/65/EU, 2002/95/EC, and 2010/571/EU	Directive (EU) 2015/863 of March 31, 2015, which amends Annex II of Directive 2011/65/EC on the restriction of the use of certain hazardous substances. The supplier confirms that the product complies with the applicable requirements of these directives, as well as the applicable requirements of the original RoHS Directives 2002/95/EC as last amended by Commission Decision 2010/571/EU. Specifically, the supplier does not intentionally add lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB's), polybrominated diphenyl ethers (PBDE's), bis(2-ethylhexyl) phthalates (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) or diisobutyl phthalate (DIBP) to the resin, nor are such substances present, to the best of the supplier knowledge, in any of the raw materials used in the product's manufacture.
REACH EC/1907/2006 and Substances of Very High Concern (SVHC), Annex XIV and XVII	The supplier confirms that the product does not contain any of the substances included on the current Candidate List of Substances of Very High Concern (SVHC) under REACH. Substances appearing in the EU REACH regulation's Annex XVII are not deliberately added to the formulation of the product at levels above the maximum concentration values specified.
2000/53/EC heavy metals directive and amendments	The product complies with the applicable requirements of this directive. Specifically, the supplier does not deliberately add lead, mercury, cadmium, or hexavalent chromium to the product, nor are such substances present, to the best of the supplier's knowledge, in any of the raw materials used in the product's manufacture.
EU 94/62/EC, EN 13428, CR 13695-2; EC 1272/2008 (Packaging Waste Directive)	Based on the reviewed documentation, the above listed resin does not contain lead, cadmium, mercury or hexavalent chromium at a concentration of 100 ppm (total) or above, thus satisfying the essential requirements of the Directive 94/62/EC Packaging Regulations for heavy metals that are in force as of the date of this letter. The resin grade is in conformance with the applicable requirements.
EU Directive 2002/96/EC and 2012/19/EU (WEEE)	No ingredients are used in the manufacture of the product which require selective waste treatment (As, Hg, PCB, PCT, CFC, HCFC, HFC, brominated flame retardants).
EC 1895/2005 (BADGE, BFDGE, NOGE)	The supplier does not deliberately add certain epoxy derivatives (e.g. NOGE, BFDGE, BADGE) to the product, nor are such substances present, to the best of the supplier's knowledge, in any of the raw materials used in the manufacture of the product.
Canada Domestic Substances List	All components of this product are in compliance with the chemical inventory.
Japanese and Chinese regulations on reportable substances	All components of this product are in compliance with the chemical inventory.
ICH Guideline Q3C(R6)	Supplier states ICH/Q3C "Impurities: Guideline for Residual Solvents" requirements are not applicable for this product.
ICH Guideline Q3D on Elemental Impurities	Complies
Conflict Minerals	Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com
Pharmacopoeia	
European Pharmacopoeia,	The supplier stated that the product meets the general stipulations of Eight Edition (2014), monographs 3.1.3 and 3.1.5.

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Raw Material Number: 8-0042-31 (continued)**Allergen Information**

Consumer Protection Act of 2004

The supplier does not deliberately add to the product any food allergens, specifically peanuts, peanut oil, any peanut product, tree nuts (almonds, brazil nuts, chestnuts, filberts, hazelnuts, hickory nuts, macadamia nuts, Queensland nuts, pecans, pine nuts, pistachios, cashews, and walnuts), wheat (gluten), milk (casein), milk products, dairy products, dairy derivatives, lactose with protein, eggs or egg products, soybeans, soy flour, any soy products, fish (bass, flounder, cod, salmon), fish products, shellfish, crustaceans (e.g. shrimp, crabs, lobsters, oysters, clams, scallops, crayfish), molluscs (e.g. snails, clams, squid, octopi) or mollusc products, sulfites, sulfur dioxide, nitrites, food colors, celery or celery products, seeds (e.g. cotton, poppy, sesame, sunflower, mustard) or seed products, aspartame, monosodium glutamate (MSG), caffeine, hydrolyzed vegetable protein (HVP), grains (e.g. rye, barley, oats, spelt, kamut), or lupine or lupine products; nor are these substances present, to the best of the supplier's knowledge, in any of the raw materials used in the manufacture of the product.

OtherGenetically Modified
Organisms (GMO)

The supplier does not deliberately add GMOs to the product, nor are such substances present, to the best of the supplier's knowledge, in any of the raw materials used in the manufacture of the product.

Kosher Certification

The supplier does not deliberately add to the product any kosher offending constituent substances, nor are such substances present, to the best of the supplier's knowledge, in any of the raw materials used in the product's manufacture. Consequently, the supplier has no reason to suspect that any would be present in the product. The supplier anticipates no difficulty in obtaining formal kosher certification with the use of this product.

Halal Certification

The supplier does not deliberately add to the product any halal offending constituent substances, nor are such substances present, to the best of the supplier's knowledge, in any of the raw materials used in the product's manufacture. Consequently, the supplier has no reason to suspect that any would be present in the product. The supplier anticipates no difficulty in obtaining formal halal certification with the use of this product.

Presence of Following
Substances and Chemicals:Plant based material
Residual SolventsAbsence of Following
Substances and Chemicals:

Bisphenol A and certain epoxy derivatives (NOGE, BFDGE, BADGE)
Bisphenol AP, AF, B, BP, C, E, F, G, M, P, and S
Latex or natural rubber (including natural rubber latex and dry natural rubber)
Melamine
Nitrosamines
Perfluorinated tensides, PFT (e.g. perfluorooctanoic acid, PFOA; perfluorooctyl sulfonates, PFOS)
Polyfluoroalkyl (PFAS)
Silicones (including surface active)
Vinyl chloride, vinylidene chloride, PVC or PVDC

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Substances of Animal Origin (BSE/TSE)

Regulation 999/2001

The supplier does not deliberately add to the resin any animal-derived substances (including bovine or tallow-derived substances), or any animal substances that may carry the risk of transmitting Bovine Spongiform Encephalopathy (BSE) or Transmissible Spongiform Encephalopathy (TSE), nor are such substances present in any of the raw materials used in the resin's manufacture. The raw materials used in the manufacture of the resin contain no animal by-products. The supplier has no reason to suspect that any animal-derived materials would be present in the resin.

Food Contact

Commission Regulation (EU) 10/2011 (as amended), (EC) No. 1935/2004, and (EC) No. 2023/2006 (GMP)

The resin complies with the European Union's food contact regulations including the Framework Regulation (EC) No. 1935/2004, Regulation (EC) No. 2023/2006 (GMP) and Regulation (EU) No. 10/2011, as amended, Annex I (including Table 1, Union list of authorised substances) and Annex II. The resin complies with the national regulations of the EU member states and non-EU countries which have adopted the European Union legislation. The resin's components are subject to Specific Migration Limits (SML) or other restrictions; based on the use amounts, articles up to 360 µm (14.2 mil) thick composed solely of the resin will comply without testing. The resin does not contain intentionally introduced dual-use additives.

US FDA 21 CFR

This product meets the requirements as described in the FDA regulations 21 CFR 177.1520 for olefin polymers, para. (c) 3.2a and may be used in the United States as an article or component of an article intended for use in contact with food, without food-type restrictions, under Conditions of Use A-H (21 CFR 176.170(c) Table 2). The information cited is subject to good manufacturing practice, technical suitability, and any limitations which are part of the regulations.

Canadian Health Products and Food Branch (HPFB) Status

A "Letter of No Objection" for this product has been approved by Health Canada. HPFB has no objection to the use in Canada of the subject resin in food-contact applications for which the resin is technically suitable.

China GB 9685 Status

All additives deliberately introduced into the subject resin grade are listed in China's "Standard for Uses of Additives in Food Contact Materials and Articles" (GB 9685-2016). The resin's components are subject to Specific Migration Limits (SML) or other restrictions; based on the use amounts, articles up to 360 µm (14.2 mil) thick composed solely of the resin will comply without testing.

Applicable Regulations

Coalition of Northeastern Governors (CONEG and TPCH)

The supplier does not deliberately add cadmium, hexavalent chromium, lead or mercury to the resin. The supplier has carried out testing on representative grades and the above heavy metals were not detected. The resin does not contain the above heavy metals at concentrations of 100 ppm (total) or above, thus satisfying the requirements of the CONEG and TPCH Model Toxics in Packaging Legislation, the California Toxics in Packaging Prevention Act (California Health and Safety Code, §25214.11-25214.21), and EU Directive 94/62/EC Packaging Regulations for heavy metals, as amended.

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.

Ozone-Depleting Chemicals

This resin does not contain and is not manufactured with Class I or Class II Ozone-Depleting chemicals. The resin does not require labeling under 40 CFR 82, subpart E (U.S. Stratospheric Ozone Protection Regulations, Labeling of Products using Ozone-Depleting Substances). In addition, the resin does not contain, and is not manufactured with any atmospheric ozone layer – depleting chemicals cited in the Montreal Protocol of 1987, as amended.

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Raw Material Number: 8-0049-06 (continued)

Restriction of Hazardous Substances (RoHS 3) - (EU) Directive 2015/863 which amends Annex II of 2011/65/EU (RoHS 2) and 2002/95/EC (RoHS)	The supplier confirms that the product complies with the applicable requirements of Directive (EU) 2015/863, which amends Annex II of Directive 2011/65/EC on the restriction of the use of certain hazardous substances, as well as the applicable requirements of the original RoHS Directive 2002/95/EC as last amended by Commission Decision 2010/571/EU. The supplier does not intentionally add lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB's), polybrominated diphenyl ethers (PBDE's), bis(2-ethylhexyl) phthalates (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) or diisobutyl phthalate (DIBP) to the resin, nor are such substances present, to the best of the supplier's knowledge, in any of the raw materials used in the resin's manufacture.
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 or substances from the Annex XVII lists above 0.1% in the product. Nor have any of these substances been intentionally added during the manufacture of the product.
2000/53/EC Heavy Metals Directive and Amendments	The resin complies with the applicable requirements of this directive. The supplier does not deliberately add lead, mercury, cadmium, or hexavalent chromium to the product, nor are such substances present, to the best of the supplier's knowledge, in any of the raw materials used in the resin's manufacture.
Directive 94/62/EC (Packaging Waste Directive)	This resin conforms to the Directive 94/62/EC on packaging and packaging waste.
EU Directive 2002/96/EC and 2012/19/EU (WEEE)	No ingredients are used in the manufacture of the product which require selective waste treatment (As, Hg, PCB, PCT, CFC, HCFC, HFC, brominated flame retardants).
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).
ICH Guideline Q3C(R6) for Residual Solvents	This resin does not contain any Class 1, 2 or 3 residual solvents identified in Guideline Q3C (R6).
ICH Guideline Q3D on Elemental Impurities	The supplier does not deliberately add Arsenic, Cadmium, Mercury, Lead, Cobalt, Vanadium, Nickel, Silver, Gold, Iridium, Osmium, Palladium, Platinum, Rhodium, Ruthenium, Selenium, Thallium, Barium, Chromium, Lithium, Molybdenum, Copper, Antimony, Tin, or their chemical compounds, nor are such substances deliberately added to any of the raw materials used in the resin's manufacture.
Conflict Minerals	Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com

Allergen Information

Food Allergens	The supplier does not deliberately add to the product any food allergens such as: peanuts, peanut oil, any peanut products, tree nuts (almonds, brazil nuts, chestnuts, filberts, hazelnuts, hickory nuts, macadamia nuts, Queensland nuts, pecans, pine nuts, pistachios, cashews, and walnuts), wheat (gluten), milk (casein), milk products, dairy products, dairy derivatives, lactose with protein, eggs or egg products, soybeans, soy flour, any soy products, fish (e.g. bass, flounder, cod, salmon), fish products, shellfish, crustaceans (e.g. shrimp, crabs, lobsters, oysters, clams, scallops, crayfish), molluscs (e.g. snails, clams, squid, octopi) or mollusc products, sulfites, sulfur dioxide, nitrites, food colours, celery or celery products, seeds (e.g. cotton, poppy, sesame, sunflower, mustard) or seed products, aspartame, monosodium glutamate (MSG), caffeine, hydrolyzed vegetable protein (HVP), grains (e.g. rye, barley, oats, spelt, kamut), or lupine or lupine products; nor are these substances present, in any of the raw materials used in the manufacture of the resin. The supplier does not specifically analyze for the presence of the above-mentioned substances and has no reason to suspect that they would be present in the resin.
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Raw Material Number: 8-0049-06 (continued)**Other**

Genetically Modified Organisms (GMOs)	This resin is not produced using genetically modified organisms (GMOs).
Halal and Kosher	The supplier does not deliberately add to the resin any kosher or halal offending constituent substances.
Presence of Following Substance	Trace levels of BHT are present in a component of one of the raw materials used in the resin's manufacture. However, residual BHT levels in the resin will not exceed, and are expected to be well below 1ppm.
Absence of Following Substances and Chemicals:	Bisphenol A and certain epoxy derivatives (e.g. NOGE, BFDGE, BADGE) Bisphenol AP, AF, B, BP, C, E, F, G, M, P and S Latex or natural rubber (including natural rubber latex and dry natural rubber) Melamine Nitrosamines (e.g. N-nitrosodimethylamine (NDMA)) Ortho-phthalates Per- and Polyfluoroalkyl substances (PFAS) Perfluorinated tensides, PFT (e.g. perfluorooctanoic acid, PFOA; perfluorooctyl sulfonates PFOS) Plasticisers (adipates, phthalates e.g.: BBP, DBP, DEHP, DnHP, DIDP, DINP, DNOP) Silicones Vinyl chloride, vinylidene chloride, PVC or PVDC

Raw Material Number: 8-0071-06**Raw Material Description:
Polypropylene 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 supplier does not use tallow or any other animal derived materials in the manufacture or formulation of this resin.

Food ContactCommission Regulation EU
10/2011 (and amendments)

The resin conforms to the applicable sections of Regulation (EC) 1935/2004 on materials intended to come into contact with food. The monomers and additives used to produce this resin are listed in EU Regulation 10/2011 and/or amendments. No monomers with a restriction are used. This resin contains substances subject to Specific Migration Limits (SML's) of 1, 3.6 and 5 mg/kg. This resin also contains a dual-use additive in its formulation. Migration can be affected by the conversion process so only the converter to the final item can guarantee the limit is not exceeded.

US FDA 21 CFR

This material meets the FDA requirements outlined in the Code of Federal Regulations 21 CFR 177.1520(a)(1)(i) and (c)1.1a. According to the supplier's information, all other ingredients used in the formulation meet their respective FDA regulations and 21 CFR 177.1520(b). Specifically, this resin meets the FDA criteria for food contact including cooking applications. This resin can be used for all food types under Conditions of Use A through H listed in 21 CFR 176.170(c), Table 2.

Applicable RegulationsCoalition of Northeastern
Governors (CONEG and TPCH)

The supplier does not use cadmium, chromium, lead, or mercury in the manufacture or formulation of this resin. In addition, this resin meets the CONEG limitation of 100 ppm for the total incidental content of cadmium, chromium, lead, and mercury.

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.

Regulation EC No. 1005/2009
on Substances that deplete the
Ozone layer

The supplier does not use Class I or Class II ODCs listed in the Resolution 1005/2009/EC in the formulation of this resin.

Restriction of Hazardous
Substances (RoHS 3) - Directive
2011/65/EU, Annex II, as amended
2015/863/EU

This resin conforms to the RoHS 3 Directive 2015/863/EU, 2011/65/EU and/or amendments restricting the use of Heavy Metals, PBB's, PBDE's, and phthalates.

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.

2000/53/EC Heavy Metals Directive
and amendments

The quantity of Pb, Hg, Cd, and Cr present in this grade is deemed below the limits given in Annex II (Note) of the Decision 2002/525/EC of June 27th (amending Annex II of Directive 2000/53) which establishes: 0.1% Pb, 0.1% Cr, 0.1% Hg, and 0.01% Cd.

Toxic Substances Control Act (TSCA)
section 6(h)

This resin 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)

The supplier does not use 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (BADGE), bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers (BFDGE) or novolac glycidyl ethers (NOGE) in the manufacture or formulation of this resin. The supplier does not test this resin for these substances.

European Directive (94/62/EC)
Packaging and Packaging Waste

This resin conforms to the European Commission Directive 94/62/EC (Article 11) and its amendments on packaging and packaging waste.

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Raw Material Number: 8-0071-06 (continued)

ICH Guideline Q3C(R6) for Residual Solvents	The supplier states that there is potential for a Class II solvent to be present in the resin grade. If any solvents were found to be present, the levels would be expected to be below the concentration limit set in the Guideline for Residual Solvents Q3C (R6).
ICH Guideline Q3D on Elemental Impurities	None of the following elements are intentionally used in the formulation of the resin grade: Cd, Pb, As, Hg, Co, V, Ni, Ti, Au, Pd, Ir, Os, Rh, Ru, Se, Ag, Pt, Li, Sb, Ba, Mo, Cu, Sn, or Cr. The supplier does not routinely test the resin for these substances.
Conflict Minerals	Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com
Pharmacopoeia	
US Pharmacopeia (USP)	This resin has been certified as a USP Class VI Plastic (USP, Biological Reactivity Tests, In Vivo).
European Pharmacopoeia (Ph. Eur.)	This resin passes the EP 3.1.6 for Containers for Parenteral Preparations.
Allergen Information	
Consumer Protection Act of 2004	The supplier does not use allergens - as defined by FDA as Milk, Eggs, Fish, Crustaceans, Wheat, Sesame, Soy, Peanuts, Tree Nuts - in the formulation of this resin.
EU Regulation 1169/2011	Complies
Other	
Genetically Modified Organisms (GMO)	The resin may utilize a component partially produced from plant material of unknown genetic origin in its formulation.
Kosher Certification	The supplier does not certify this resin to be Kosher or in compliance with Kosher requirements.
Presence of Following Substances and Chemicals:	Preservatives Palm oil or Soybean oil
Absence of Following Substances and Chemicals:	The supplier does not intentionally use any of the following substances in the manufacture or formulation of this resin: "natural rubber latex", "dry natural rubber", "synthetic latex", Bisphenol A (BPA), Bisphenol S (BPS), Melamine, Perfluorooctanoic Acid (PFOA), Perfluorooctane Sulfonate (PFOS), Polyvinyl Chloride (PVC), Phthalates, Nitrosamines, and Nitroso Compounds.

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Substances of Animal Origin (BSE/TSE)

Regulation 999/2001

There are no animal derived components known to be present in the raw materials or introduced during the manufacture of this product.

Food Contact

US FDA 21 CFR

The components in this product have not been assessed for food contact compliance according to US FDA 21 CFR.

Commission Regulation
EU 10/2011

The components in this product have not been assessed for food contact compliance according to the European Commission Regulation EU 10/2011.

Applicable Regulations

Coalition of Northeastern
Governors (CONEG and TPCH)

This product complies with the requirements of the Coalition of Northeastern Governors (CONEG) Model toxics legislation on heavy metals, which requires total incidental content of Cadmium (Cd), Lead (Pb), Chromium (Cr) and Mercury (Hg) to be <100 ppm. The supplier does not routinely analyze for these specific substances and does not deliberately add cadmium, hexavalent chromium, lead or mercury to this product.

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) - (EU)
Directive 2015/863, 2011/65/EU
and amendments

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 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 or substances from the Annex XIV and XVII lists above 0.1% in the product. Nor have any of these substances been intentionally added during the manufacture of the product.

2000/53/EC Heavy Metals
Directive and Amendments

The product complies with the applicable requirements of this directive. The supplier does not deliberately add lead, mercury, cadmium, or hexavalent chromium to the product.

Toxic Substances Control Act
(TSCA)

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

Phthalates (EU) Directives
2005/84/EC and 2015/863/EU

This product meets the requirements of EU Directive 2005/84/EC. No phthalate esters, including di-(2-ethylhexyl) phthalate (DEHP), di-n-butyl phthalate (DBP), butyl benzyl phthalate (BBP), di-isononyl phthalate (DINP), di-isodecyl phthalate (DIDP), di-n-octyl phthalate (DNOP), diisobutyl phthalate (DIBP) are intentionally included in the manufacture or formulation of this product. The supplier does not routinely analyze for these specific chemicals. This information is based on the supplier's vendors' certificates or letters of compliance.

Directive 2012/19/EU
(WEEE) and Annex VII

This product meets the relevant requirements of this directive.

US Clean Air Act and
Montreal Protocol

The supplier does not manufacture this product with, intentionally formulate it with, or use in the production process, any Class I or Class II substances including CFCs, HCFCs, HBFCs, halons, carbon tetrachloride, methyl chloroform, methyl bromide, or bromochloromethane.

Conflict Minerals

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

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Raw Material Number: 8-0099-06 (continued)**Pharmacopoeia**

European Pharmacopoeia

European Pharmacopoeia testing was not completed on this product.

Allergen Information

Consumer Protection Act of 2004

This product does not include ingredients derived from the following allergens identified in the Food Allergen Labeling and Consumer Protection Act of 2004: milk, egg, fish, shellfish, tree nuts, wheat gluten, peanuts and soybeans.

European Regulation 1169/2011

The product is not intentionally manufactured or formulated with any of the following: Cereals containing gluten, crustaceans, eggs or egg products, fish, peanuts, milk or dairy products, tree nuts, celery, mustard, sesame seeds, lupin, or molluscs.

Other

Genetically Modified Organisms (GMO)

This product is not produced using genetically modified organisms (GMO).

Presence of Following Substances and Chemicals:

Plant derivatives

Absence of Following Substances and Chemicals:

4,4'-Bisphenol A (BPA)
Bisphenol S (BPS)
Latex
Melamine
Natural latex rubber
Nitrosamines or nitrosating agents
Per- and Polyfluoroalkyl substances (PFAS)
Perfluorooctanoic acid (PFOA)
Perfluorooctane sulfonic acid, its salts (PFOS / PFOS-F)
Perfluorooctane Sulfonyl fluoride (PFOSF)
Phthalates
Plant based material
Polyvinyl Chloride (PVC)
Silicone

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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

California Proposition 65

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

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

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 (FALCPA)</i> ; 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: 8-0099-74**Raw Material Description:
Blue 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, Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as amended, and Commission Regulation (EU) No. 10/2011, as amended prior to September 2020 (as the supplier is currently working with the raw material suppliers in order to confirm genotoxicity) or the 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. This concentrate contains one or more monomers and/or additive(s) that are regulated with a specific migration limit. This concentrate contains 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 selected to formulate the color concentrate are either "generally recognized as safe" (GRAS), prior-sanctioned, acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act based upon legal opinion and/or supplier certification, subject to an effective Food Contact Notification (FCN), exempt from regulation under 21CFR170.39 - Threshold of Regulation (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): 174, 175, 176, 177, 178, 181, 182, 184, and 186. The ingredients selected to manufacture this concentrate are acceptable to contact food of types A through H. Based upon the agreed letdown ratio of 2%, the color concentrate 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.

Applicable RegulationsCoalition of Northeastern
Governors (CONEG and TPCH)

Based on documentation for the raw materials used to formulate the color concentrate was reviewed for compliance with the CONEG Legislation. The concentrate is not formulated to contain lead, cadmium, mercury or hexavalent chromium above the allowable level of 100ppm. 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.

Toxic Substances Control Act
(TSCA)

This concentrate 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 - Directive 2011/65/
EU (RoHS 2, as amended by
2015/863/EU (RoHS 3), and China
RoHS 2 (GB/T 26572)

Based on supplier documentation, the color concentrate as formulated, 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.

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Raw Material Number: 8-0099-74 (continued)

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 colorant nor are there substances from the Annex XVII listed with restrictions for the container/closure application above 0.1%. Nor have any of these substances been intentionally added during the manufacture of the product.
94/62/EC, 2005/20/EC, and 2013/2/EU (Packaging Waste Directive)	Based on the reviewed documentation, the color concentrate was not formulated to contain lead, cadmium, mercury or hexavalent chromium above the allowable level of 100ppm total. 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.
2002/96/EC and 2012/19/EU (WEEE)	The documentation for the raw materials used to formulate the color concentrate has been reviewed for compliance with WEEE Directive 2002/96/EC and 2012/19/EU. Based on the compliance 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 complies with the WEEE Directives 2002/96/EC and 2012/19/EU.
ICH Guideline Q3C(R6) for Residual Solvents	Information not available.
ICH Guideline Q3D on Elemental Impurities	Information not available.
Phthalates	The documentation for the raw materials used to formulate the color concentrate has been reviewed for any indication of the presence of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), di-n-octyl phthalate (DNOP), (tris(2-carboxyethyl)phosphine (TCEP), tris(chloropropyl) phosphate (TCPP), Tris(1,3-dichloroisopropyl)phosphate (TDCPP), Polychlorinated Terphenyls (PCTs), and Tri-substituted organic tin compounds. There was no indication of the listed substances are present in the raw materials. The color concentrate was not formulated to contain the listed substances and they are not intentionally introduced during the manufacture of the color concentrate. 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

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 <i>Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)</i> ; 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 and soybean oil was found.
EU Regulation No. 1169/2011	The documentation for the raw materials used to formulate the color concentrate has been reviewed for any indication that allergens per EU Regulation 1169/2011, Annex II are present in the raw materials. There was no indication that the noted substances were found. The color concentrate was not formulated to contain allergens per EU Regulation 1169/2011, Annex II and they are not intentionally introduced during the manufacture of the color concentrate. This declaration is based on formulation and supplier information, not based on testing.

Other

Genetically Modified Organisms (GMO)	Genetically Modified Organisms (GMO) are present in the raw materials used to formulate this concentrate.
Presence of Following Substances and Chemicals:	Plant Derived Material
Absence of Following Substances and Chemicals:	Bisphenol A (BPA) - 4,4'-isopropylidenediphenol Bisphenol S (BPS) Latex/natural rubber Melamine Nitrosamines Ortho Phthalates PFOA/PFOS/PFAS Polyvinyl chloride (PVC) 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)

European guidance document
2011/C73/01

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.

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 and is also suitable for use in medical devices 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 concentrate are listed in the 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. This concentrate contains one or more monomers and/or additives that are regulated with a specific migration limit.

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): Parts 174, 175, 176, 178, 181, 182, 184 and 186.

Applicable Regulations

Coalition of Northeastern
Governors (CONEG and TPCH)

Based on 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.

Restriction of Hazardous
Substances (RoHS 3) - Directive
2011/65/EU, as amended by
2015/863/EU, Annex II

As formulated, this compound complies with EU RoHS Directive 2011/65/EU (RoHS 2), as amended by 2015/863 (RoHS 3) and does not contain any restricted materials above threshold levels. The RoHS Directive restricts the use of lead, cadmium, chromium VI, mercury, PBBs, PBDE, DBP, DEHP, BBP, and DIBP materials, and limits the levels of all substances to 0.1%, except for Cadmium 0.01%.

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Raw Material Number: 8-0099-75 (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).
ICH Guideline Q3C(R6) for Residual Solvents	No supplier information available.
ICH Guideline Q3D on Elemental Impurities	No supplier information available.
China RoHS 2 – GB/T 26572	As formulated, this compound complies with China RoHS 2 (GB/T 26572) and does not contain any restricted materials above threshold levels.
REACH EC/1907/2006 Substances of Very High Concern (SVHC), Annex XIV and XVII	The supplier confirms that the product does not contain any of the substances included on the current Candidate List of Substances of Very High Concern (SVHC) under REACH. There is no presence of SVHCs or substances from the Annex XVII list above 0.1% in the product. Nor have any of these substances been intentionally added during the manufacture of the product.
Packaging Waste Directive 94/62/EC, 2005/20/EC, 2013/2/EU, and 2002/96/EC (WEEE)	The documentation for the raw materials used to formulate the color concentrate have been reviewed for compliance with WEEE Directive 2002/96/EC and 2012/19/EU. The color concentrate complies with the WEEE Directive 2002/96/EC and 2012/19/EU. Based on documentation review, the color concentrate was not formulated to contain lead, cadmium, mercury or hexavalent chromium above the allowable level of 100 ppm total. The color concentrate comply 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. It does not exclude the presence of traces due to impurities or residuals in the components supplied by third parties and used in the suppliers production facilities.
Conflict Minerals	Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com

Allergen Information

Consumer Protection Act of 2004	The color concentrate has been reviewed for any indication of the eight major substances considered allergens per the <i>Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)</i> ; 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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Other

Genetically Modified Organisms (GMO)	Genetically Modified Organisms (GMO) are present in the raw materials used to formulate this concentrate.
Presence of Following Substances and Chemicals:	Acrylic Acid 2,6-di-tert-butyl-p-cresol Plant Derived Material Vinyl Acetate Zinc
Absence of Following Substances and Chemicals:	Bisphenol A (BPA) Bisphenol S (BPS) Latex Melamine Nitrosamines Ortho-phthalates PFOA/PFOS/PFAS Phthalates Polyvinyl chloride (PVC) Silicone

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