



Nalgene Polypropylene Copolymer (PPCO) bottles, flasks, funnels and jugs

Product regulatory guide

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

ISO Certificate link:

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

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

Date: March 31, 2022

How to use this guide

Scope of this publication

This Product Regulatory Guide (PRG) offers a wealth of material formulation and regulatory information for Thermo Scientific™ Nalgene Polypropylene Copolymer (PPCO) bottles, flasks, funnels, and jugs. As of the date of this publication, the information provided is current and correct.

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

The Key Product Specification Table includes (where applicable):

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

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

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

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



Materials of construction

Catalog Number	Material Information	
	Component Part Number	Description
Polypropylene Copolymer Bottles w/Closures and Jugs w/Closure		
2006-XXXX	8-0028-03	Polypropylene Copolymer (PPCO) Bottle Resin
2016-XXXX	8-0071-06	Polypropylene (PP) Closure Resin
2105-XXXX		
2187-XXXX		
2203-0005		
2203-0010		
2221-0010		
312016-XXXX		
312105-XXXX		
312110-0008		
312187-XXXX		
<hr/>		
2405-XXXX	8-0028-03	Polypropylene Copolymer (PPCO) Bottle Resin
	8-0071-06	Polypropylene (PP) Closure Resin
	8-0099-74	Blue Colorant
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2121-00XX	8-0028-03	Polypropylene Copolymer (PPCO) Bottle Resin
	8-0071-06	Polypropylene (PP) Closure Resin
	8-0099-34	White Colorant
2115-XXXX		
<hr/>		
2126-XXXX	8-0028-03	Polypropylene Copolymer (PPCO) Bottle Resin
	8-0071-06	Polypropylene (PP) Closure Resin
	8-0099-34	White Colorant
	8-0005-30	TPE Closure Resin
2203-0020		
2221-0020		
<hr/>		
Erlenmeyer Flasks and Volumetric Flasks		
4000-XXXX	8-0028-03	Polypropylene Copolymer (PPCO) Resin
	8-0071-06	Polypropylene (PP) Closure Resin
<hr/>		
4102-XXXX	8-0028-03	Polypropylene Copolymer (PPCO) Bottle Resin
<hr/>		
Separatory Funnel with Closure		
4300-XXXX	8-0028-03	Polypropylene Copolymer (PPCO) Resin
	8-0071-06	Polypropylene (PP) Closure Resin
	8-0099-43	Black Colorant

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Catalog Number	Material Information (continued)	
	Component Part Number	Description
Dispensing Bottle with Closure		
DS2420-0125	8-0028-03	Polypropylene Copolymer (PPCO) Bottle Resin
DS2420-0250	8-0071-06	Polypropylene (PP) Closure Resin
	8-0099-74	Blue 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

Legal Manufacturer	
Nalgene Nunc International Corporation, A part of Thermo Fisher Scientific Inc. 75 Panorama Creek Drive, Rochester, NY 14625	
Shelf-Life	Thermo Fisher Scientific does not provide expiry dates for these products.
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	2115-XXXX 2405-1000
Separatory Funnels Leak Tested at 2 psi for 2 minutes	4300-XXXX
Leak Tested at 2 psi for 2 minutes	2006-XXXX, except 2006-9125, 2016-XXXX, 2105-XXXX, 2126-XXXX, 2187-XXXX, 2221-XXXX, 2405-XXXX, 312016-XXXX, 312105-XXXX, 312187-XXXX
Ink Adhesion Test	2405-0500 2405-1000
Acetone Rub Test for Ink Adhesion	2405-0500 2405-1000
Hot Stamp Ink Adhesion and Impression Test	4000-XXXX
Flasks Shake Leak Tested for 10 Seconds	4102-XXXX
Autoclavable at 15 psig for 15 minutes (Closure systems larger than 100mm)	DS2420-XXXX, 2006-XXXX, 2016-XXXX, 2105-XXXX, 2115-XXXX, 2187-XXXX, 2221-XXXX, 2126-XXXX, 312016-XXXX, 312110-XXXX, 4000-XXXX, 4300-XXXX

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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*
- USP Class VI Plastic – tested per USP <88>, Biological Reactivity Tests, In Vivo*
- FDA Compliance – 21 CFR
- USP <661> Physicochemical Tests

*For test method details, contact ROCRegSupport@ThermoFisher.com

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>

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.

Material information sheets

Raw Material Number: 8-0005-30

Raw Material Description: Thermoplastic Elastomer (TPE) 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 (EC) No. 999/2001
The supplier does not deliberately add any animal-derived substances that may carry the risk of transmitting Bovine Spongiform Encephalopathy (BSE) or transmissible Spongiform Encephalopathy (TSE). The raw materials used in the manufacture of the product contain no animal by-products.

Food Contact

Commission Regulation EU 10/2011 (and amendments)
This product meets the relevant requirements of European Union regulation 2023/2006 on materials and articles intended to come into contact with food. The product complies with Regulation (EU) No. 10/2011 involving plastic materials intended to come into contact with food as amended by EU regulations 321/2011, 1282/2011, 1183/2012, 202/2014, 174/2015, 1416/2016, 752/2017, 79/2018, 213/2018, 831/2018, 37/2019, 1338/2019 and 1245/2020 (which repeals Directive 2002/72/EC as amended). All additives and polymers used to manufacture this product are compliant with the relevant requirements of EU regulation 10/2011 as amended on plastic materials and articles intended to come into contact with food.

US FDA 21 CFR
This product is acceptable for use in food contact applications under 21 CFR 177.1810(b)(3) and holds a Food Contact Notification (FCN). This allows for the product to be used as a component of finished articles intended to contact all food types (FDA Food Types I through IX; 21 CFR 176.170 Table 1) and Conditions of Use A through H (21 CFR 176.170 Table 2). All of the components used in the manufacture of this product comply with the Code of Federal Regulations (CFR) Section 21, Part 177.1210 and 177.2600.

Applicable Regulations

Coalition of Northeastern Governors (CONEG) and EU Directive 94/62/EC (Packaging Waste Directive)
The supplier does not deliberately add cadmium, hexavalent chromium, lead or mercury to the product, thus satisfying the requirements of the CONEG and TPCH Model Toxics in Packaging Legislation and EU Directive 94/62/EC Packaging Regulations for heavy metals, as amended.

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

Clean Air Act of 1990
This product does not contain any of the Class I or Class II Ozone-Depleting Substances as listed in the Clean Air Act of 1990.

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Raw Material Number: 8-0005-30 (continued)

Restriction of Hazardous Substances (RoHS 3) - (EU) Directive 2015/863 which amends Annex II of 2011/65/EU and 2002/95/EC	Based on the supplier's knowledge, Directive (EU) 2015/863, 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 Directive 2002/95/EC. 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.
China "RoHS 2" Regulation	The supplier does not intentionally add or use lead, mercury, hexavalent chromium, polybrominated biphenyl (PBB) and polybrominated diphenyl ether (PBDE) flame retardants, at levels greater than 0.1%; cadmium at levels greater than 0.01%; and Pentabromodiphenylether, Octabromodiphenylether, and Decabromodiphenyl oxide, in concentrations higher than 0.1%. Please note that the supplier does not routinely test for these materials.
REACH EC/1907/2006 and Substances of Very High Concern (SVHC), Annex XIV and XVII	The supplier confirms that the product should not contain the substances included on the current Candidate List of Substances of Very High Concern (SVHC) or the Annex XVII list of restrictions above the applicable threshold (0.1%) under REACH. Nor have any of these substances been intentionally added during the manufacture of the product.
2000/53/EC (ELV) 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, 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 Directive 2002/96/EC and 2012/19/EU (WEEE)	This product has not been assessed for compliance.
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.
Consumer Product Safety Improvement Act of 2004	This product meets the requirements of the Consumer Product Safety Improvement Act of 2004.
Directive 2002/61/EC, amending 76/769/EEC	This product is compliant with Directive 2002/61/EC of the European Parliament and of the Council of 19 July 2002, amending the Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations.
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).
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	Based on the information provided to the TPE resin supplier by its raw material suppliers and their formulation reviews, this resin could possibly contain a potential source of residual solvent(s). Solvents are not intentionally added by the resin supplier during the production process, nor as raw material components. The solvent(s) may be present as residual solvent(s) from raw material component(s) used in the resin. Please note that the supplier does not routinely test for these substances.

Continued next page

Raw Material Number: 8-0005-30 (continued)

ICH Guideline Q3D on Elemental Impurities	The supplier confirms that none of the following elements are intentionally used in the formulations of this resin: As, Cd, Pb, Hg, Co, V, Ni, Ti, Au, Pd, Ir, Os, Rh, Ru, Se, Ag, Pt, Li, Sb, Ba, Mo, Cu, Sn, or Cr. Testing for these elements has not been performed on the product.
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Conflict Minerals

Request for a conflict minerals statement should be directed to:

conflict.minerals@thermofisher.com

Pharmacopoeia

European Pharmacopoeia	The supplier has not conducted any EU Pharmacopoeia testing on this TPE resin.
US Pharmacopoeia (USP)	The supplier tested this TPE resin and it met the requirements of USP Class VI and ISO 10993-4 and -5.

Allergen Information

EU Regulation 1169/2011, amending 1924/2006/EC and 1925/2006/EC	The supplier does not deliberately add to the product any food allergens such as: peanuts, tree nuts, milk, eggs, wheat, soybeans, fish and Crustacean shellfish, 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.
Food Allergen Labeling & Consumer Protection Act of 2004 (FALCPA)	No major food allergens such as milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat and soybeans. One of the TPE resin supplier's raw material suppliers states that their facility processes highly refined soybean based materials; therefore trace amounts of soy may be present. No soy protein is used in their manufacturing processes and none is used in their facility.

Other

Genetically Modified Organisms (GMO)	Based on the information provided to the TPE resin supplier by its raw material suppliers and their formulation reviews, this resin may contain Genetically Modified Organisms (GMOs). The supplier does not routinely test for these substances.
Kosher Certification	The supplier has not certified the resin as Kosher or in compliance with Kosher guidelines.
Halal Certification	The supplier has not certified the resin as Halal or in compliance with Halal guidelines.
Presence of Following Substances and Chemicals:	Calcium stearate Dilauryl.beta.-thiodipropionate Proprietary antioxidants 1,3,5-Triazine-2,4,6(1H,3H,5H)-trione,1,3,5,-tris[3,5-bis(1,1-dimethylethyl)-4hydroxyphenyl]- Plant derivative(s)
Absence of Following Substances and Chemicals:	Bisphenol (BPA, BPF, and BPS) Latex, Natural Rubber Latex, or Natural Rubber Melamine Nitrosamines / N-nitrosamines Nitrosamines or Nitroso compounds Perfluorooctane sulfonates (PFOS, PFOA) Phthalates (DAP, BBP, DBP, DEHP, DCHP, DEP, DiBP, DIDP, DINP, DiPP, DMP, DMEP, DnHP, DnOP, DNP, and DPP/DPENP) Polyvinyl chloride (PVC) Silicone

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Substances of Animal Origin (BSE/TSE)

Regulation 999/2001

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

Food Contact

Commission Regulation EU 10/2011 (and amendments)

The 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 in the formulation. This product contains substances subject to Specific Migration Limits (SML's) of 0.3, 1, and 1.5 mg/kg. Migration can be affected by the conversion process, so only the converter to the final item can guarantee the limits are not exceeded.

US FDA 21 CFR

This material meets the FDA requirements outlined in the Code of Federal Regulations 21 CFR 177.1520(a)(3)(i) and (c)3.2a. 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 product meets the FDA criteria for food contact including cooking applications. This product can be used for all food types under Conditions of Use A through H listed in 21 CFR 176.170(c), Table 2.

Applicable Regulations

Coalition of Northeastern Governors (CONEG) and TPCH

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

California Proposition 65

This product does not contain any components or 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 Ozone Depleting Chemicals (ODCs)

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

Restriction of Hazardous Substances (RoHS 3) - Directive 2011/65/EU, 2002/95/EC, 2015/863/EU

This product 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.

China "RoHS 2" Regulation

The supplier does not intentionally use Lead, Mercury, Cadmium, Hexavalent Chromium, Polybrominated Biphenyls (PBB's), or Polybrominated Diphenyl Ethers (PBDE's) in the formulation of the grades mentioned above. The supplier does not routinely test these products for these substances.

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 product. The supplier does not test this product for these substances.

2002/96/EC and 2012/19/EU (WEEE)

The supplier confirms that no heavy metals (antimony, arsenic, barium, cadmium, chromium, lead, mercury, selenium, hexavalent chromium, or silver), polybrominated biphenyls (PBB's), polybrominated diphenyl ethers (PBDE's), or Deca Brominated Diphenyl Ethers (Deca BDE's) are intentionally added to any of the grades mentioned above. The fact that these metals/ substances are not intentionally used, does not exclude that trace levels of these substances may be present as a result of the raw materials used to produce these products. The supplier does not routinely test these products for these substances.

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Raw Material Number: 8-0028-03 (continued)

Heavy Metals Directive 2000/53/EC (ELV)	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.
Phthalates	The resin supplier has indicated that phthalates are not intentionally added in the formulation of this resin, however there may be phthalates in the resin as a result of catalyst residues. The supplier has performed analytical testing and determined specific phthalates may be present in concentrations less than 5 ppm.
94/62/EC, 2005/20/EC, and 2013/2/EU (Packaging Waste Directive)	This product conforms to the European Commission Directive 94/62/EC (Article 11) and its amendments on packaging and packaging waste.
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 states there is potential for Class II and III solvents to be present in this product. The supplier believes if these solvents are present they will be well below the concentration limit set in the Guideline for Residual Solvents Q3C(R6).
REACH EC/1907/2006 Substances of Very High Concern (SVHC), Annexes XIV and XVII	The supplier confirms that the resin does not contain any of the substances listed on the current Candidate List of Substances of Very High Concern (SVHC), Annexes XIV and XVII under REACH at levels greater than 0.1%. Nor have any of these substances been intentionally added during the manufacture of the product.
ICH Guideline Q3D on Elemental Impurities	The supplier confirms that none of the following elements are intentionally used in the formulation of this product: 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. Testing for these elements has not been performed on this 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).
Conflict Minerals	Request for a conflict minerals statement should be directed to: conflict.minerals@thermofisher.com
Pharmacopoeia	
Pharmacopoeia USP <88>	This product meets the standards set by the United States Pharmacopoeia USP <88> Biological Reactivity Tests, In Vivo- Class VI Plastics.
European Pharmacopoeia	This product meets the requirements of European Pharmacopoeia 3.1.6. "Polypropylene for Containers and Closures for Parenteral and Ophthalmic Preparations."
Allergen Information	
Consumer Protection Act of 2004	Allergens such as: peanuts, tree nuts, milk, eggs, wheat, soy, fish and crustaceans are not intentionally used in the manufacture or formulation of this resin.
European Regulation 1169/2011	Allergens, including but not limited to those listed in EU Regulation 1169/2011 such as: peanuts, tree nuts, milk, eggs, wheat gluten, soybeans, fish and shellfish are not used as additives or raw materials in the manufacture of this resin.
Other	
Genetically Modified Organisms (GMO) Plant Origin	This product utilizes a component produced from palm oil in its formulation. No GMO are used in the formulation of this resin.
Kosher Certification	The supplier of this resin does not certify this polypropylene resin to be Kosher or in compliance with Kosher requirements.
Presence of Following Substances and Chemicals:	Slip agents (amides)
Absence of Following Substances and Chemicals:	The supplier does not intentionally use any of the following substances in the manufacture or formulation of this product: "natural rubber latex", "synthetic latex", Bisphenol A (BPA), Bisphenol S (BPS), Melamine, Perfluorooctanoic Acid (PFOA), Perfluorooctane Sulfonate (PFOS), Polyvinyl Chloride (PVC), Nitrosamines.

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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 Contact

Commission 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 Regulations

Coalition 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.

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

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.
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.

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.

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.

Commission Regulation EU
10/2011 (and amendments)

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.

Continued next page

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</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 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)

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 Contact

Commission 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 Regulations

Coalition of Northeastern
Governors (CONEG) and TPCP

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.

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.

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Raw Material Number: 8-0099-43 (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.
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Other

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)

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 Contact

Commission 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 Regulations

Coalition 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 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.
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 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 and soybean oil was found.
European Regulation 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.

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

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

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