



# Nalgene Amber HDPE bottles and carboys

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>

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Date: March 02, 2022

# How to use this guide

## Scope of this publication

This Product Regulatory Guide (PRG) offers a wealth of material formulation and regulatory information for Thermo Scientific™ Nalgene™ Amber HDPE bottles and carboys. 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 Series	Material Information	
	Component Part Number	Description
2004-XXXX		
2009-XXXX		
2106-XXXX		
2256-7020		
312004-XXXX	8-0042-31	High Density Polyethylene (HDPE) Bottle Resin
312009-XXXX	8-0097-17	Opaque Amber Colorant
312085-XXXX	8-0071-06	PP Closure Resin
312106-XXXX		
312185-XXXX		
322004-XXXX		
322085-XXXX		
	8-0042-31	High Density Polyethylene (HDPE) Bottle Resin
312084-XXXX	8-0099-16	Translucent Amber Colorant
312184-XXXX	8-0071-06	PP Closure Resin
	8-0097-17	Opaque Amber Colorant
362004-XXXX	8-0042-31	High Density Polyethylene (HDPE) Bottle Resin
362085-XXXX	8-0097-17	Opaque Amber 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  
75 Panorama Creek Drive  
Rochester, NY 14625

### Shelf-Life

No shelf life certification provided.

### Product Release Testing

#### Visual Inspection

Time-based in-process visual inspection is performed on a sampling of parts during production.

#### Dimensional Inspection

Time-based in-process dimensional inspection is performed on a sampling of parts during production.

#### Performance Inspection (Leak Testing)

Time-based in-process performance inspection is performed on a sampling of parts during production.

#### Vacuum Leak Test at 2.5 psi for 2 minutes

312004-9125, 312084-9125, 322004-9125, 362004-9125

#### Leak Tested at 2 psi for 2 minutes

2004-XXXX  
2009-XXXX  
2106-XXXX  
2256-7020  
312009-XXXX  
312085-XXXX  
312106-XXXX  
312184-XXXX  
312185-XXXX  
322085-XXXX  
362085-XXXX  
312004-XXXX except -9125  
312084-XXXX except -9125  
322004-XXXX except -9125  
362004-XXXX except -9125

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**Certifications**

Biocompatible – materials meet the requirements of:

- ISO 10993-5:2009 Biological evaluation of medical devices- Part 5: Tests, In Vitro Cytotoxicity
- USP 33 <88> Biological Reactivity Tests, In Vivo

Exclusion: 8-0042-31 & 8-0099-16 blend

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

ISO Certificate link:

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

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## Material information sheets

**Raw Material Number: 8-0099-16**

**Raw Material Description:  
Translucent AMBER 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 999/2001

An ingredient material used in one or more of these products may contain substances produced from tallow from animal sources. The animal species can be porcine, ovine, caprine and/or bovine and originate from North American sources, but the age of the animal stock or its feeding practices are not available. In addition, the animal-sourced substance is processed in accordance with European Council Decision 1999/534/EC; these processing conditions include hydrolysis (splitting) at 200°C at corresponding pressure for at least 20 minutes, while additional processing may also be performed. These substances comply with the EMEA 410/01 Rev. 3 and ISO 22442-1 (Annex C Section C.5 on tallow derivatives), but the manufacturing facility is not registered as ISO 22442-1 compliant. The use of the substance is as a polymer processing aid.

If present, identification of animal and country of origin

The product contains one or more ingredients (tallow derived) that are derived from porcine, ovine, caprine, and/or bovine tallow that originates from North American sources.

### Food Contact

Commission Regulation EU 10/2011 (and amendments)

Please be advised that this product, pursuant to Commission Regulation (EU) No. 10/2011 as amended (up to (EC) 37/2019), is acceptable for use with plastic materials and articles intended to come into contact with food. This Regulation is a specific measure within the meaning of Article 5(1) of Regulation (EC) No. 1935/2004. This Regulation should establish the specific rules for plastic materials and articles to be applied for their safe use and repeal Commission Directive 2002/72/EC of 6 August 2002 on plastic materials and articles intended to come into contact with foodstuffs. Additionally, colorants used in this product meet the purity requirements specified under AP (89)1.

US FDA 21 CFR

Please be advised that this product, when used at the recommended letdown ratio in the prescribed resins, is acceptable for food contact applications regulated under the provisions of the Food, Drug, and Cosmetic Act and subsequent amendments as outlined in Title 21 of the Code of Federal Regulations for use in all food types under temperature conditions A through H as described in Tables 1 and 2, Section 176.170(c). Applicable sections of 21 CFR are identified below for the intended end use product as identified by your company: 21 CFR 177.1520(c)3.2a, 21 CFR 178.3297, and 21 CFR 178.2010

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**Raw Material Number: 8-0099-16 (continued)****Applicable Regulations**

Coalition of Northeastern Governors (CONEG)	Based on the information provided to the supplier by its raw material suppliers and the supplier's formulation reviews, the product contains no lead, mercury, cadmium or hexavalent chromium. Please note that the supplier does not routinely test for these materials. The supplier certifies that they do not intentionally add or use these materials in the manufacture or handling of this product at or above restricted concentrations.
California Proposition 65	The supplier has assessed this colorant based on the current list published by the Office of Environmental Health Hazard Assessment (OEHHA://oehha.ca.gov/proposition-65). The supplier's evaluation has shown that no exposure warning is required for this colorant.
Ozone Depleting Substances	Based on the information provided to the supplier by its raw material suppliers and the supplier's review of the product formula, the supplier determined the product does not contain any Ozone Depleting substances (Class I & II). The supplier does not routinely test for these substances. The supplier certifies that ozone-depleting ingredient materials are not intentionally added or used in the manufacturing or handling of this product.
EC Directives on Waste Electrical and Electronic Equipment (WEEE) & (ROHS), RECAST 2011/65/EU & Directive (EU) 2015/863	Based on the information provided to the supplier by its raw material suppliers and the supplier's formulation reviews, the supplier has found that this product does not contain RoHS/WEEE substances above listed concentrations and would therefore be in compliance with the European RoHS/WEEE regulation. Please note that the supplier does not routinely test for these materials. The supplier certifies that they do not intentionally add or use these materials in the manufacture or handling of this product at or above restricted concentrations.
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 at or above applicable thresholds in the product. Nor have any of these substances been intentionally added during the manufacture of the product.
EC 1895/2005 (BADGE, BFDGE, NOGE)	Regarding the potential use of bis phenol F, also known as BPF, bis phenol S, also known as BPS, bis phenol A – diglycidyl ether, also known as BADGE, bis phenol F – diglycidyl ether, also known as BFDGE or novolac glycidyl ethers, also known as NOGE within the product. Based on the information provided to the supplier by its raw material suppliers and their formulation review, they have found that this product does not intentionally contain BPF, BPS, BADGE, BFDGE or NOGE substances. Please note they do not routinely test for BPF, BPS, BADGE, BFDGE or NOGE. The supplier certifies that they do not intentionally add or use BPF, BPS, BADGE, BFDGE or NOGE in the manufacture or handling of 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).
ICH Guideline Q3C(R6) for Residual Solvents	The supplier does not test this product to this standard.
ICH Guideline Q3D on Elemental Impurities	Based on the information provided to the supplier by its suppliers, they have found that this product may contain trace amounts of an elemental substance. Specifically, this product is formulated with one or more raw materials that intentionally contain zinc. Please note that this product has not been subjected to testing in order to identify the presence of these substances.

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**Allergen Information**

Consumer Protection Act of 2004 and European Regulation 1169/2011

The product does not intentionally contain any of the following substances identified as food allergens or derivatives of these food allergens: peanuts, crustacean shellfish, fish, eggs, tree nuts, milk (including lactose), wheat, soybeans, cereals containing gluten (i.e., wheat, rye, barley, oats, or their hybridized strains), nuts (including almonds, hazelnuts, walnuts, cashews, pecan nuts, Brazil nuts, pistachio nuts, macadamia nuts), celery, sesame seeds, mustard, lupin, mollusks, sulphites at concentrations > 10 mg/kg or 10 mg/L expressed as SO<sub>2</sub>, and sulfur dioxide. Also note that the facilities which manufacture this product may handle epoxidized soybean oils, which are refined, deodorized and bleached, but they are a derivative of soybean; Good Manufacturing Procedures prevent the likelihood of cross contamination.

**Other**

Genetically Modified Organisms (GMO)

The supplier has completed an evaluation of the product ingredient formulation and the materials handling and processing procedures used to produce this product. Based on the information provided to the supplier by its raw material suppliers and review of its product formula and processes, the supplier finds that this product should not include any genetically modified organism ingredient materials. Please note that the supplier does not routinely test for these materials.

Presence of Following Substances and Chemicals:

Zinc

Absence of Following Substances and Chemicals:

BPA  
 BPS  
 Latex-derived ingredients/Dry Natural Rubber/Natural Rubber Latex  
 Melamine or melamine formaldehyde polymeric ingredient materials  
 Nitrosamines  
 PVCPhthalates  
 Plant derived materials  
 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.
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### 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: <a href="mailto:conflict.minerals@thermofisher.com">conflict.minerals@thermofisher.com</a>
<b>Pharmacopoeia</b>	
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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**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 protien (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.

**Other**

Genetically 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 Solvents

Absence 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)  
Polyfluoroalky (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 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: <a href="mailto:conflict.minerals@thermofisher.com">conflict.minerals@thermofisher.com</a>
<b>Pharmacopoeia</b>	
US Pharmacopeia (USP)	This resin has been certified as a USP Class VI Plastic (USP, Biological Reactivity Tests, In Vivo).
European Pharmacopoeia,	This resin passes the EP 3.1.6 for Containers for Parenteral Preparations.
<b>Allergen Information</b>	
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
<b>Other</b>	
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](https://www.ema.europa.eu/en/documents/scientific-guideline/minimizing-risk-transmitting-animal-spongiform-encephalopathy-agents-human-veterinary-medicinal_en.pdf)), FDA guidance on Medical Devices Containing Materials Derived from Animal Sources (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-devices-containing-materials-derived-animal-sources-except-vitro-diagnostic-devices>) and/or ISO 22442-1 Annex C.5 (<https://www.iso.org/obp/ui/#iso:std:iso:22442:-1:ed-3:v1:en>).

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

If present, identification  
of animal and country of origin

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

### Food Contact

Commission Regulation EU  
10/2011 (and amendments)

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

US FDA 21 CFR

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

### Applicable Regulations

Coalition of Northeastern  
Governors (CONEG) and TPCH

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

California Proposition 65

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

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

Toxic Substances Control Act (TSCA) section 6(h)	This colorant was not intentionally formulated to contain decabromodiphenyl ether (DecaBDE), phenol, isopropylated phosphate (3:1) (PIP (3:1)), 2,4,6-Tris(tert-butyl)phenol (2,4,6-TTBP), hexachlorobutadiene (HCBD), or pentachlorothiophenol (PCTP).
Restriction of Hazardous Substances (RoHS 2) - Directive 2011/65/EU, Annex II, as amended by Commission Delegated Directive 2015/863/EU (RoHS 3)	As formulated, this product does not contain any substances regulated under EU RoHS Directive (2011/65/EU) (RoHS 2, as amended by 2015/863; RoHS3) and China RoHS 2 (GB/T 26572) above threshold levels.
REACH EC/1907/2006 and Substances of Very High Concern (SVHC), and Annex XVII	The supplier confirms that the product does not contain any of the substances included on the current Candidate List of Substances of Very High Concern (SVHC) under REACH. There is no presence of SVHCs or substances from the Annex lists above 0.1% in the product. Nor have any of these substances been intentionally added during the manufacture of the product.
2011/65/EU (RoHS), 2002/96/EC, and 2012/19/EU (WEEE)	Since the colorant complies with the EU "Restriction of Hazardous Substances" (RoHS) Directive (2011/65/EU) and does not contain any of the RoHS listed materials, the color concentrate also complies with the WEEE Directive 2002/96/EC and 2012/19/EU. This declaration is based on formulation and supplier information, not based on testing.
94/62/EC, 2005/20/EC, and 2013/2/EU (Packaging Waste Directive)	Based on the reviewed documentation, the above listed concentrates were not formulated to contain lead, cadmium, mercury or hexavalent chromium above the allowable level of 100ppm total. Therefore, the amber colorant complies with the Packaging Waste Directive 94/62/EC, 2005/20/EC, and 2013/2/EU. This declaration is based on formulation and supplier information, not based on testing.
Conflict Minerals	Request for a conflict minerals statement should be directed to: <a href="mailto:conflict.minerals@thermofisher.com">conflict.minerals@thermofisher.com</a>
ICH Guideline Q3C(R6) for Residual Solvents	The documentation for the raw materials used to formulate this color concentrate has been reviewed for any indication of the presence of the substance(s) noted. However, there was no indication found that the substance(s) are present in the raw materials. In addition, this color concentrate was not formulated to contain any of the noted substance(s) and the substance(s) are not intentionally introduced during the manufacture of this concentrate.
ICH Guideline Q3D on Elemental Impurities	The documentation for the raw materials used to formulate the color concentrate has not been analyzed for the presence of elemental impurities referenced in the International Conference on Harmonisation's ICH Q3D Guideline for Elemental Impurities. The supplier of the color concentrate is not required to comply with guidelines set by the International Conference on Harmonisation's ICH Q3D Guideline for Elemental Impurities. The ICH Q3D guidelines require the manufacturers of finished products to comply with the guidelines.
<b>Allergen Information</b>	
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, soybean oil, was found.
<b>Other</b>	
Genetically Modified Organisms (GMO)	Based on supplier information Genetically Modified Organisms (GMOs) are present in the raw material.

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

**Other**

Presence of Following Substances: Plant Derived Material

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Absence of Following  
Substances and Chemicals:

- Bisphenol A (BPA)
- Bisphenol S (BPS)
- Latex/Natural rubber
- Melamine
- Nitrosamines or Nitrosating agents
- Ortho phthalates
- PFOA/PFOS/PFAS
- Phthalates
- Polyvinyl chloride (PVC)

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