### Performance

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<th>Question</th>
<th>Answer</th>
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| What are the standard Quality Control tests performed on each lot of Thermo Scientific™ Nalgene™ bottles? | • Performance – leak test  
• Visual – embedded particulates, color, clarity, chamfer (bottle), seal ring (closure)  
• Dimensional – wall thickness, threads |
| How does the closure system work on Nalgene Bottles?                    | • There is a chamfer (beveled edge) formed on the inside neck of the bottle that mates with the seal ring formed inside the closure to form a leak proof seal when the proper torque is applied.  
• Although some Nalgene closures may thread onto non-Nalgene bottles or non-Nalgene closure thread onto Nalgene bottles, there is no guarantee the combined system will be leakproof unless both are Nalgene. |
| What is the difference between leakproof and leak resistant containers? | • A leakproof container is batch controlled and guaranteed not to leak under specified conditions  
• Many Nalgene bottles are tested at 2 psi for 2 minutes with water  
• A leak resistant container has no leakproof guarantee |
| How are the Thermo Scientific Nalgene bottles tested for leakproofness? | • The standard bottle/closure leak test is described in our online catalog or on www.thermoscientific.com/packagingbottles |
| What is torque?                                                         | • Application Torque is a measure of force used to apply a closure to a bottle  
• Recommended application torque values can be found in our online catalog or on www.thermoscientific.com/packagingbottles  
• Removal Torque is the measure of force required to remove a closure from a bottle.  
• Removal torque is typically 50% less than application torque. |
| Please define black spec contamination – what is acceptable, what are they? | • Black specs are typically the result of degraded material breaking free from (and inherent to) the manufacturing process and being molded into the bottle.  
• Every Nalgene bottle has a maximum number and size for embedded black spec contamination  
• For example a bottle between 3” and 12” cannot have more than 2 particles greater than 0.020” in size.  
• The operator packing the bottles at the machine inspect bottles under general factory lighting for black specs and have the ability to reject any bottles that do not pass. |
| What Thermo Scientific Nalgene Bottles are certified to be low particulate? | • Our 382099 series bottles are manufactured in a controlled environment to minimize particulate contamination.  
• These bottles are certified to have an average of <30 particles per ml > 0.03 microns |
### What bottles are autoclavable (121°C @15 psi (103 kPa) for 20 minutes)?
- Bottles and carboys made from Polypropylene (PP), Polypropylene Copolymer (PPCO), Polycarbonate (PC), Teflon® FEP and PFA are autoclavable.
- Bottles and carboys made from Low-density polyethylene (LDPE), High-density polyethylene (HDPE), Polyethylene terephthalate (PET) and Polethylene terephthalate copolyester (PETG) are not autoclavable as they will deform at this high temperature.

### Can Nalgene bottles be easily labelled and/or directly printed?
- Nalgene Packaging bottles have a registration notch molded in the bottom for accurate positioning in labelling machine or printers.
- Direct printing requires upfront flame treatment (Nalgene bottles are not flame treated at the factory).

### Can I freeze dry (lyophilize) product in Thermo Scientific Nalgene containers?
- In order to successfully lyophilize, the container needs a very flat bottom surface (especially for long storage/shelf life applications). Only our PETG Serum Vials have a flat bottom and product can be lyophilized successfully. However, the moisture transmission rate through the walls of the PETG vials is high enough to affect the freeze dried product inside the vial.

### Can I use our Thermo Scientific Nalgene bottles and carboys in an oven?
- No – the plastics used to manufacture Nalgene products are not compatible with the heat from an oven.

### Where do I find chemical compatibility information on Thermo Scientific Nalgene bottles?
- Chemical compatibility information can be found in our online catalog or on [www.thermoscientific.com/packagingbottles](http://www.thermoscientific.com/packagingbottles).
# Regulatory Certification

## Question

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<thead>
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<th>Question</th>
<th>Answer</th>
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| Which Thermo Scientific Nalgene Bottles can be certified ADCF (Animal Derived Component Free)? | • Bottle resins PET, PETG, HDPE, PP, PPCO, Teflon are all ADCF  
• Closure resins HDPE, PP & Teflon are all ADCF  
• Colored closures and bottles are not ADCF as the colorant carrier resin has a trace amount of animal derived component in it.  
• Regulatory Affairs group @ rocregsupport@thermofisher.com should be your first call to address any specific customer related request.                                                                                                                                                                                                                                                                                  |
| What bottle materials are compliant with CFR (Code of Federal Regulation) 21 for food contact? | All resins used to make Thermo Scientific Nalgene bottles and closures are compliant with CFR 21 for food contact.                                                                                                                                                                                                                                                                                                                                                                        |
| How do I obtain product certificates of compliance and certificates of irradiation for Thermo Scientific Nalgene products? | • Product certificates of compliance and certificates of irradiation (this one available for sterile products only) are available at [www.thermoscientific.com/certificates](http://www.thermoscientific.com/certificates) or can be requested at certificateroc@thermofisher.com.                                                                                                                                                                                                                                                                                                                                 |
| Are the Thermo Scientific Nalgene bottles UN Certified? | • All and only IP2 bottles are UN certified as inner packaging and suitable for air transport  
• Our IP2 bottles are suitable for packaging hazardous materials for air transport include:  
  - 2099-series Narrow Mouth HDPE Bottles – lab pack  
  - 312099-series Narrow Mouth HDPE Bottles – bulk pack  
  - 2199-series Wide Mouth HDPE Bottles – lab pack  
  - 312199-series Wide Mouth HDPE Bottles – bulk pack  
 Each manufacturing lot of these bottles is leak tested at 15 psi (103 kPa) for 30 minutes with water.  
A certificate stating compliance with this testing is included with each case.  
Many other Thermo Scientific Nalgene bottles and micro packaging vials may be suitable for air transport of non-hazardous materials.  
It is the responsibility of the end user to insure their entire package complies with the air transport regulations.                                                                                                                                                                                                                                                                                                           |
| Are the Thermo Scientific Nalgene bottles RNase/DNase free? | Only the Sterile Thermo Scientific Nalgene Micro Packaging Vials are certified RNase/DNase free.                                                                                                                                                                                                                                                                                                                                                                                                  |
| Are the Thermo Scientific Nalgene bottles Pyrogen free? | All and only Sterile Thermo Scientific Nalgene are certified to be non-pyrogenic. Endotoxin testing detection limits prevent a product from being considered Pyrogen free.                                                                                                                                                                                                                                                                                                                     |
| What Thermo Scientific Nalgene bottles are certified as compliant with USP testing for light transmission? | • All Amber and White Thermo Scientific Nalgene bottles are suitable for storing and shipping light sensitive products.  
• All Amber and White Thermo Scientific Nalgene bottles and closures meet the requirements of light resistant containers per USP criteria. USP criteria states that the container cannot allow more than 10% light transmission for any wavelength between 290 and 450 nanometers.                                                                                                                                                                                                                                                                 |
| Are the Thermo Scientific Nalgene bottles compliant with European Union regulatory requirements? | Most resins are tested for and compliant with the EU modified abnormal toxicity test.  
• Regulatory Affairs group @ rocregsupport@thermofisher.com should be your first call to address EU regulatory compliance requirements.                                                                                                                                                                                                                                                                                                                                         |
### What is the difference between leachable and extractable data?

- **Extractables** - Chemical entities that migrate from any product contact material when exposed to an appropriate solvent under exaggerated conditions of time and temperature. The solvents and conditions are meant to be extremely aggressive and designed to represent “worst case” results.
- **Leachables** - Chemical compounds that are typically a subset of extractables that can migrate from the contact material into stored solutions under normal process conditions and or accelerated conditions. Leachable studies are designed to produce results representative to actual application and use of the products.

### Do you have leachable/extractable data?

The following forced extraction studies on our line of Nalgene Bottles, Carboys, and Biotainers are available for sales and under confidentiality agreement:

- 105-0001, Thermo Scientific Nalgene PETG Bottles (System)
- 105-0002, Thermo Scientific Nalgene InVitro PC Biotainers (Rochester, System)
- 105-0003, Thermo Scientific Nalgene PP Carboys (System)
- 105-0004, Thermo Scientific Nalgene InVitro PETG Biotainers (System)
- 105-0005, Thermo Scientific Nalgene Invitro PC Biotainers (Newport, System)
- 105-0007, Thermo Scientific Nalgene Sterile HDPE Carboy (System) *this one covers also natural HDPE bottles*

Please reach out to our technical support group at [technicalsupport@thermofisher.com](mailto:technicalsupport@thermofisher.com) for further info and details.

- Leachables studies can be performed on behalf of customer as charged service
- Please reach out to our technical support group at [technicalsupport@thermofisher.com](mailto:technicalsupport@thermofisher.com) for further info and details
- Most resins used to manufacture Nalgene bottles meet latest biological testing standards including USP Class VI, USP <661>, USP citotoxicity, EP abnormal toxicity

### What is a Nalgene Validation Binder?

The Nalgene Validation Binders have been developed to verify that Nalgene products meet the highest standards for quality and workmanship in the industry. They provide excellent baseline data to support customer validation requirements. They contain proprietary data which pertain to product and resin info and testing (biological, performance, dimensional), specifically developed to promote the use of Nalgene products in pharmaceutical, diagnostic, and biotech applications.

- Validation binders are material (resin) specific

### How do I get a validation binder and/or a forced extraction study for my customer?

- A request on company letterhead (of the customer’s company) needs to be submitted to [rocregulatory@thermofisher.com](mailto:rocregulatory@thermofisher.com)
- A confidentiality agreement is required as the information contained within the validation binder and the forced extraction studies is considered confidential to Thermo Fisher Scientific and the distribution of this information needs to be controlled.

### Where do I get information on bottle materials regarding topics such as BPA, REACH, etc.?

- Regulatory Affairs group @ [rocregsupport@thermofisher.com](mailto:rocregsupport@thermofisher.com) should be your first call for this information
## General Information

<table>
<thead>
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<th>Question</th>
<th>Answer</th>
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<td>Where are the Thermo Scientific Nalgene bottles manufactured?</td>
<td>• All Thermo Scientific Nalgene bottles are manufactured in our Rochester, NY facilities. Mid 2014 Nalgene PET square media bottles will begin to be manufactured at our facility in Newport (UK) in addition to Rochester.</td>
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| What is ISO Class 7?                                                    | • ISO Class 7 is a classification of a cleanroom and refers to a specific particulate level in the air of a manufacturing environment. It is closest to the class 10,000 FED Standard 209E i.e. <10,000 particles of size 0.5 um or larger are permitted per cubic foot of air.  
  • Currently our PETG Media Bottles, Serum Vials, Roller Bottles and Biotainers are manufactured in Class 7 cleanrooms.  
  • Newport line to manufacture PET square media bottles also will be running in an ISO Class 7 certified cleanroom. |
| How do I know a product is made by Thermo Scientific Nalgene?           | • There is a finished goods label on every carton of Nalgene products. On this label is a description and lot number.  
  • Many products have Nalgene molded into the base of the bottle or the closure (or both).  
  • Nalgene micro packaging vials have an “N” molded into the neck of the vial (just above the knurls). |
| What do the first two numbers in the 10 digit product code mean?         | • 31 is a bulk pack, bottles and closures packed separately within the same carton.  
  • 32 is a shrink wrapped tray pack.  
  • 33 is a bulk pack with closures assembled onto the bottles.  
  • 34 is sterile product (usually packed within a tray).  
  • 36 is either a bottle or closure bulk packed separately in a separate carton. |
| What does the closure designation (e.g. 20-415) mean?                   | • The first number is the inner diameter of the closure in mm, the second refers to the neck finish of the bottle. |
| How do I get replacement closures?                                      | • Small quantities (i.e. 12 each per pack) are available as 712150 series.  
  • Large quantities (i.e. 1000 each per case) are available as 362150 series (13-415 through 38-430). |
| Does Thermo Scientific Nalgene offer tamper evident containers?         | • Shrink bands are offered to fit our 20-415, 24-415 and 38-430 bottle neck finishes. They are used on PET/PETG Media Bottles and placed over the closure and neck ring of the bottle and then shrunk into place with a heat source (typically a heat gun for a short period of time).  
  • We have new tamper evident closures with a tear off ring available to fit with 38-430 PET and PETG media bottles (and from beg. of 2014 also pre-assembled to the PET media bottles). |
| What is the difference between PET and PETG?                            | • PET and PETG have similar performance characteristics; however they are two chemical different resins.  
  • PET needs to be stretched (ISBM) as part of the manufacturing process in order to optimize CO₂/O₂ barrier properties.  
  • PET costs significantly less than PETG and therefore produces a product at a lower price point.  
  • PETG is a much heavier wall bottle and is more durable than PET, especially in frozen applications. |
| What is the difference between Bulk Pack Packaging Bottles and Bulk Pack Laboratory Bottles? | • Bulk Pack bottles are available in two slightly different versions, Packaging and Laboratory grade.  
  • Both grades are designed in a packaging format (typically large quantity per case and closures not assembled) ideal for production (OEM) customers.  
  • The packaging grade has anonymous (not Nalgene branded) components (closures and bottles), made of less plastic (lighter) and therefore cheaper (economy version).  
  • The Laboratory grade has Nalgene branded components (closures and bottles), made of more plastic (heavier) and therefore with overall superior durability. |
| Why do we not offer any sterile Polypropylene Copolymer bottles?         | • Gamma irradiation is our standard method for sterilizing bottles. Polypropylene Copolymer is not resistant to gamma radiation and will become brittle and discolor significantly. |
| How do I get a special product?                                         | • A special is a minor modification to standard or existing product in accordance with customer requests, such as sterility, packaging configuration, labeling, special certification, Q/C requirements or other specifications attainable by existing tooling, approved materials for the base product, and procedures.  
  • Submit request via [www.salesforce.com](http://www.salesforce.com) — Cases — Customer inquiry for a special  
  • Minimum manufacturing quantities and order value apply for all specials. Additional information will come from your commercial contact. |
| Why do specials take so long to manufacture?                            | • Most specials are manufactured for a specific customer and are “make to order” meaning the production planning process does not start until the order is placed.  
  • The lead time for a special product is dependent on the manufacturing production schedule and how a particular special fits within the existing schedule. |
Contacts

Where do I find contact information for Commercial, Product Management etc.:  
- Technical Support should be your first call for technical related information @ technicalsupport@thermofisher.com
- Regulatory Support should be your first call for regulatory compliance information @ roc-regulatory@thermofisher.com
- For Certificates: certificateroc@thermofisher.com
- Product Manager Packaging: Rodolfo Merola @ rodolfo.merola@thermofisher.com
- Packaging Landing page: www.thermoscientific.com/packagingbottles

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