



**Thermo Scientific Nalgene Carboys  
for Vaccines and Biologics**

**superior containers**  
maximize product security

**Thermo**  
SCIENTIFIC

## All carboys are not created equal.

# Trust the proven performance of Nalgene.

Thermo Scientific™ Nalgene™ containers are made with high quality resins, and meet the rigorous production standards.

That's why millions of Nalgene carboys and bottles are safely at work in bioproduction facilities and laboratories around the world.

Choose from a wide range of quality carboys and jerricans to fit your application requirements – from collecting and mixing reagents, media and bulk vaccines to storing active pharmaceutical ingredients.

Shatter-resistant plastic containers are less likely to break than glass. The high-quality materials and construction of Nalgene containers enhance this advantage, assuring protection for your valuable products.





## The Nalgene Carboy Difference

When selecting carboys for critical bioproduction applications, standard laboratory carboys fall far short of what is required for this highly regulated industry.

We provide the necessary application support and documentation, as well as robust customer notification process.

Customization with fluid transfer options and pre-sterilized carboys are additional benefits you can expect from the Thermo Scientific Nalgene portfolio.

Nalgene containers are made from only high quality resins that meet pharmaceutical, laboratory and foodgrade standards. Our resins are selected to minimize additives and reduce potential leachables. We do not use plasticizers or fillers, and our plastics have low total ash content – a measure of impurities.

### Nalgene carboys minimize risk, protecting your valuable products:

- Leak-proof to ensure contained materials are not lost during storage or transport
- Sterile, single-use options to eliminate the need for in-house packaging and sterilization
- Container designs that enable cleaning validations
- Sanitary fitting options for easier cleaning validations and processes
- Validation binders and forced extraction studies to support regulatory compliance needs



The qualification and validation of production, harvest and containment supplies is an integral part of any biopharmaceutical application process. Regulatory guidelines around the world recommend that the production, storage and packaging components are assessed for extractables or leachables that may interact with or impact the product being manufactured.

To support you, we commissioned studies to identify compounds that may be extracted from key components under extreme conditions and estimate the amount of these compounds. These studies are designed to help you choose the correct container to further investigate with additional extractables and leachables studies.

1

**Studies were conducted on two different Thermo Scientific Nalgene carboy systems:**

- Nalgene PP Carboys and Closures (TPE Gasket and PP white closure)
- Nalgene Sterile HDPE Carboys and Closures (PP white closure)

2

**Three extraction solvents were used on each unit for the forced extraction process:**

- Water
- Ethanol\*
- Hexanes\*
- 10% Nitric Acid\*\*

\*Direct Injection GC/MS and LC/MS analysis

\*\*ICP/OES Analysis only

3

**Each extracted solution was subsequently analyzed by:**

- Headspace Gas Chromatography/Mass Spectrometry (GC/MS) for volatile and Direct Injection GC/MS for semi-volatile organic compounds
- Liquid Chromatography/Mass Spectrometry (LC/MS) for non-volatile organic compounds
- Inductively Coupled Plasma (ICP) for metals and elemental extractables using an acid digested solution

Combined with NIST98K, Wiley and other databases, these techniques provide the information required to profile and identify any significant extractable species from each component tested. The evaluation of extractables is based on the semi-quantitative estimation of analytes obtained by these techniques.

An analysis protocol is available for review upon request under a confidential disclosure agreement (CDA), defining the strategy utilized to perform the extraction process.



In addition to forced extraction studies for the carboy systems, several other studies are available across the Nalgene Storage Solutions portfolio

#### Forced Extraction Studies

Cat. No.	Description
105-0001	Nalgene PETG Bottles (System, irradiated at 19-28 kGy)
105-0010	Nalgene PETG Bottles (System, irradiated at 20-45 kGy)
105-0002	Nalgene PC Biotainers Bottles (System, US Resin)
105-0003	Nalgene PP Carboys (System)
105-0004	Nalgene PETG Biotainers Bottles (System)
105-0007	Nalgene Sterile HDPE Carboys (System)

For specific compliance needs, you may find the following guides helpful:

FDA Guidance for Industry: Container Closure Systems for Packaging of Human Drugs and Biologics – Chemistry, Manufacturing and Controls Documentation, May, 1999

EMA Guideline on Plastic Immediate Packaging Materials, CPMP/QWP/4359/03 & EMEA/CVMP/205/04, European Medicines Agency, May, 2005.

It is important to understand the difference between extraction studies and the leachables studies.

#### Extractables Definition:

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 Definition:

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.

For more information contact us at:  
[rocregsupport@thermofisher.com](mailto:rocregsupport@thermofisher.com)



# High Density Polyethylene (HDPE) Certified Platinum Clean

## USP <788> Low Particulate Containers

### Certified Platinum Clean HDPE Carboys

Ready-to-use carboys from 10L to 33L available and validated to meet less than 1/3 the allowable particulate limits according to USP<788>. Double, heat-seal bagged and placed into twist-tied, plastic carton liners in robust, double-walled cartons. Validated sterile to SAL  $10^{-6}$  and endotoxins < 0.25 EU/mL.

- Double, heat-seal bagged and placed into twist-tied, plastic carton liners in robust, double-walled cartons.
- Validated sterile to SAL  $10^{-6}$  and endotoxins < 0.25 EU/mL.
- Containers and closures cleaned in proprietary HEPA filtered washing/drying equipment
- Clean packaged in superior packaging in Class 10 HEPA filtered workstations inside our Class 100 clean room
- Sterile and low endotoxin
- Virgin resin materials

### Recommended Applications

Bulk intermediate, etc. storage in clean room or controlled environment use

Pharmaceutical, Bioproduction and other sensitive applications



Cat. No.	Description	Volume	Width/OD, mm (in)	Height with Closure, mm (in)	Closure Size	Material	No. per PK/Cs
CE-N2289-0020	Carboy with Integrated Handles	10L (2.6 gal)	250.2 (9.85)	389 (15.3)	83B	White PP	1/6
CE-N2289-0050	Carboy with Integrated Handles	20L (5.3 gal)	284.2 (11.19)	501.7 (19.8)	83B	White PP	1/4
CE-N2289-0075	Carboy with Integrated Handles	33L (8.7 gal)	381 (15.0)	546 (21.5)	83B	White PP	1/1

## Thermo Scientific™ Clean Process Products for Critical Environments

Working within a critical environment such as a clean room necessitates high quality materials and equipment since contamination can quickly spell disaster for what are typically exceedingly sensitive applications. It is therefore essential that products used in your critical environments, such as plastic bottles, vials, carboys, caps and other materials conform to standards of cleanliness necessary.



# High Density Polyethylene (HDPE)

## Ideal for harsh conditions where excellent chemical compatibility is required

- Leak-proof PP screw top design (see page 9 for details)
- Wide range including Heavy-Duty for extra aggressive conditions, Amber for light sensitive products and Wide-Mouth design for easy filling and dispensing of liquids
- Round for homogeneous stirring
- Rectangular shape (jerrican) for efficient use of storage space
- Pre-sterilized, single use options mean no in-house sterilizing or sterilization validation required
- Suitable for conditions from -100°C to +120°C

### Recommended Applications

- Media formulation and mixing
- Aseptic protocols
- Aggressive conditions or chemicals
- Production where products may adhere to and leach out of containers



Cat No	Description	Capacity, L (gal)	Dimensions			Height with Closure, mm (in)	No. per Pk/Cs
			Closure Size, mm	Length, mm (in)	Width/OD, mm (in)		
342289-0050*	Single-Use Carboy (NOTE: must purchase handle separately below)	20 (5.3)	83B	—	284 (11.2)	502 (19.8)	1/6
342289-0075	Single Use Carboy Molded-in Handles	33 (8.7)	83B	—	381 (15.0)	546 (21.5)	1/1
2256-7020	Amber Carboy	10 (2.6)	83B	—	250 (9.8)	383 (15.1)	1/6
2097-0020	Fluorinated Carboy	10 (2.6)	83B	—	250 (9.8)	389 (15.3)	1/6
2097-0050	Fluorinated Carboy	20 (5.3)	83B	—	282 (11.1)	526 (20.7)	1/4
2211-0020	Rectangular Carboy without Spigot	9 (2.4)	100-415	220 (8.7)	153 (6.0)	360 (14.2)	1/6
2211-0050	Rectangular Carboy without Spigot	20 (5.3)	100-415	320 (12.6)	229 (9.0)	399 (15.7)	1/4
2214-0050	Heavy-Duty Rectangular Carboy	20 (5.3)	70	330 (13.0)	228 (9.0)	406 (16.0)	1/4
2241-0050**	Heavy-Duty Wide-Mouth Carboy	20 (5.3)	120	305 (12.0)	203 (8.0)	457 (18.0)	1/4
2240-0015	Jerrican Tethered Angled Closure	6 (1.5)	53B	213 (8.4)	176 (6.9)	335 (13.2)	1/6
2240-0025	Jerrican Tethered Angled Closure	10 (2.6)	53B	246 (9.7)	199 (7.8)	376 (14.8)	1/6
2240-0050	Jerrican Tethered Angled Closure	20 (5.3)	53B	320 (12.6)	245 (9.6)	452 (17.8)	1/4
2243-0013	Jerrican Tethered Top Closure	13 (3.5)	53B	290 (11.4)	189 (7.4)	378 (14.9)	1/4
2243-9013	Jerrican Tethered Top Closure, 38mm Spigot	13 (3.5)	53B, 38-430	290 (11.4)	189 (7.4)	378 (14.9)	1/4
2242-0025	Fluorinated Jerrican	10 (2.6)	53B	246 (9.7)	199 (7.8)	376 (14.8)	1/6
2242-0050	Fluorinated Jerrican	20 (5.3)	53B	320 (12.6)	245 (9.6)	452 (17.8)	1/4
<b>Accessories</b>							
2229-0001	Handle for 20 L Single-Use Carboy (Stainless Steel)						1/1
712240-1053	53B Replacement Closure and Strap for Jerrican						10/10
712160-0384	38-430 Replacement Closure for Large Nalgene Bottles						12/12
712160-0530	53B Replacement Closure for Large Nalgene Bottles or Carboys						12/12
712160-0830	83B Replacement Closure for Large Nalgene Bottle or Carboy						2/2

\* Handle must be purchased separately.

\*\* Designed for powder and solid storage – closure is not leak-proof.

# Polycarbonate (PC)

## Excellent crystal-clear glass alternative

- Leak-proof PP screw top design (see page 9 for details)
- Autoclavable for in-house sterilization
- Graduations for volume determination at a glance
- Crystal-clear like glass, yet fracture resistant even at low temps
- Smaller validation sizes are available to save on expensive process validations
- Round for homogeneous stirring
- Rectangular shape (jerrican) for efficient use of storage space

### Recommended Applications

Where full content visualization is required  
 For any protocol using glass where a safer alternative is required



Cat No	Description	Capacity, L (gal)	Closure Size, mm	Dimensions			No. per Pk/Cs
				Length, mm (in)	Width/OD, mm (in)	Height with Closure, mm (in)	
2251-0020	Round Clearboy	10 (2.6)	83B	—	253 (10.0)	394 (15.5)	1/4
2251-0050	Round Clearboy	20 (5.3)	83B	—	287 (11.3)	536 (21.1)	1/4
DS2213-0020	Rectangular Clearboy	9 (2.4)	100-415	220 (8.7)	153 (6.0)	360 (14.2)	1/1
DS2213-0050	Rectangular Clearboy	20 (5.3)	100-415	320 (12.6)	229 (9.0)	399 (15.7)	1/1
DS2127-0030	Validation Bottle	30 mL (1 oz.)	20-415	—	32 (1.3)	75 (3.0)	1/30
DS2127-0250	Validation Bottle	250 mL (8.5 oz.)	53B	—	74 (2.9)	135 (5.3)	1/6
DS2127-2000	Validation Bottle	2 (0.5)	53B	—	123 (4.8)	296 (11.7)	1/12
<b>Accessories</b>							
712160-0530	53B Replacement Closure for Large Nalgene Bottles or Carboys						12/12
712160-0830	83B Replacement Closure for Large Nalgene Bottle or Carboy						2/2
712160-0053	TPE Gasket for 53B Closure						12/12
712162-1830	TPE Gasket for 83B Closure						5/5



# Our Leak-proof Guarantee

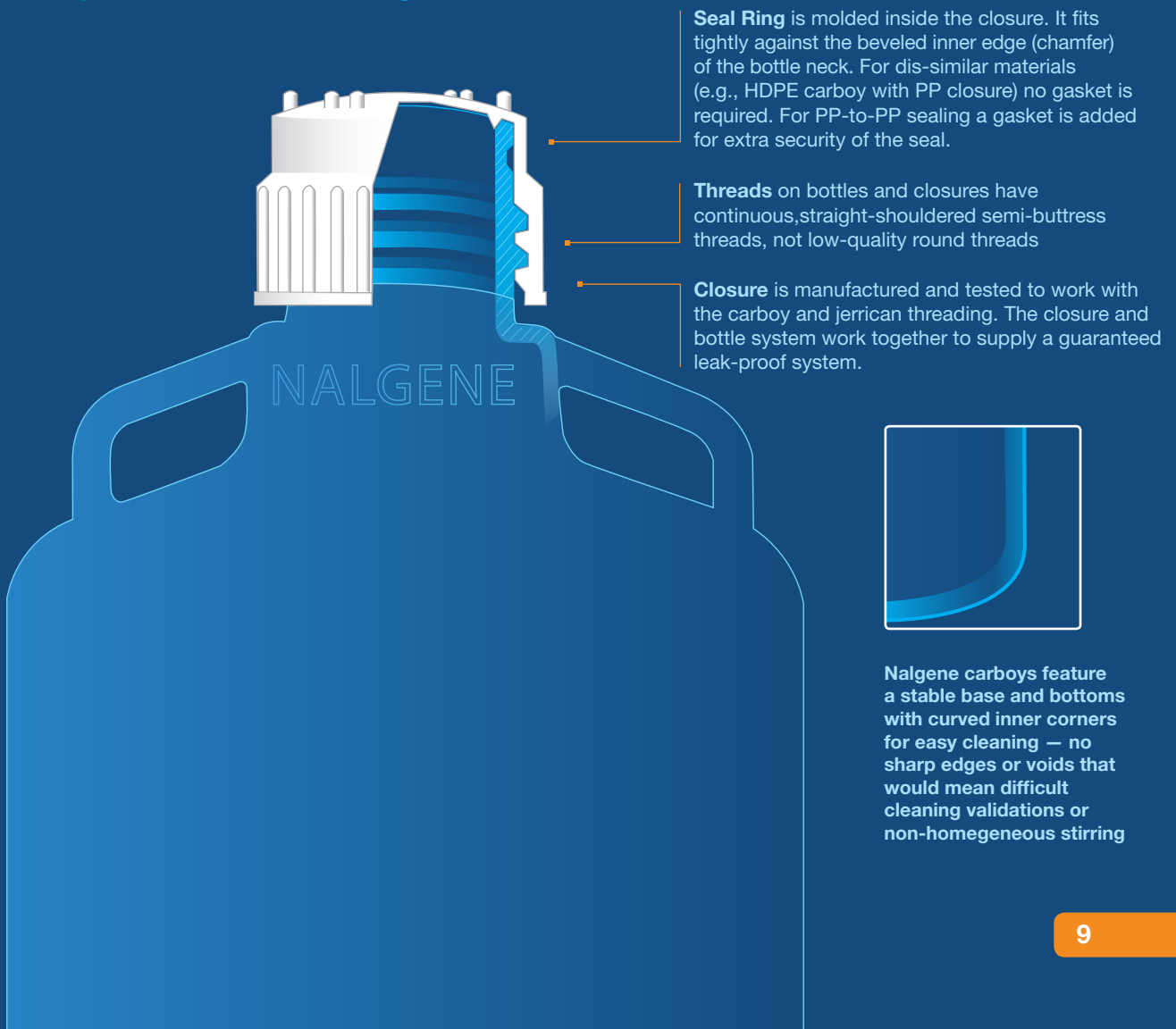
**We stand behind every Nalgene carboy and jerrican you buy.**

Nalgene carboys and closures are engineered to work together with a strong, semi-buttress thread design that prevents stripping. We offer a leak-proof guarantee because we manufacture and test both components together as part of our routine quality inspection process (see page 15 for details).

If any Nalgene container doesn't meet our leak-proof standards, simply return it to us and we will replace it – guaranteed.

## Anatomy of a Nalgene Carboy

**Thermo Scientific Nalgene carboys and closures are designed, manufactured and supported with the rigorous needs of the pharmaceutical and biologics market in mind.**



# Polypropylene (PP)

## Ideal for in-house cleaning and autoclaving

- Leak-proof PP Screwtop design with TPE gasket (see page 9 for details)
- Convenient shoulder or attached metal handles for easy carrying and pouring
- Graduations for volume determination at a glance
- Heavy-duty version for vacuum or extreme conditions
- Wide-mouth version for easy cleaning, filling and dispensing
- Version with sanitary dispensing port for use as supply reservoir
- Round shape for homogeneity during stirring
- Rectangular shape (jerrican) for efficient use of storage space



### Recommended Applications

Where autoclave-sterilization is required

Vacuum or extreme use conditions (heavy-duty)

Bulk API or other substances as reservoir for dispensing

Solid or powder material storage (Wide-Mouth)

Cat No	Description	Capacity, L (gal)	Dimensions			Height with Closure, mm (in)	No. per Pk/Cs
			Closure Size, mm	Length, mm (in)	Width/OD, mm (in)		
2212-0020	Rectangular Carboy with SS Handle	9 (2.4)	100-415	220 (8.7)	153 (6.0)	360 (14.2)	1/6
2212-0050	Rectangular Carboy with SS Handle	20 (5.3)	100-415	320 (12.6)	229 (9.0)	399 (15.7)	1/4
2226-0020	Heavy-Duty Carboy with Handles	10 (2.6)	83B	—	250 (9.8)	389 (15.3)	1/6
2226-0050	Heavy-Duty Carboy with Handles	20 (5.3)	83B	—	282 (11.1)	526 (20.7)	1/4
2235-0020	Wide-Mouth Carboy with Handles	10 (2.6)	100-415	—	250 (9.8)	343 (13.5)	1/6
2235-0050	Wide Mouth Carboy with Handles	20 (5.3)	100-415	—	282 (11.1)	483 (19.0)	1/4
2250-0020 /8250-0020 +	Carboy with Handles, Autoclavable	10 (2.6)	83B	—	250 (9.8)	389 (15.3)	1/6
2250-0050 /8250-0050 +	Carboy with Handles, Autoclavable	20 (5.3)	83B	—	282 (11.1)	526 (20.7)	1/4
2250-0130 /8250-0020 +	Carboy with Handles, Autoclavable	50 (13.2)	83B	—	379 (14.9)	678 (26.7)	1/1
2640-0020	Carboy with Sanitary Flange Bottom, Autoclavable	10 (2.6)	83B, 1-1/2 in. Tri Clover	—	250 (9.8)	389 (15.3)	1/1
2640-0050	Carboy with Sanitary Flange Bottom, Autoclavable	20 (5.3)	83B, 1-1/2 in. Tri Clover	—	282 (11.1)	526 (20.7)	1/1
2640-0130	Carboy with Sanitary Flange Bottom, Autoclavable	50 (13.2)	83B, 1-1/2 in. Tri Clover	—	379 (14.9)	678 (26.7)	1/1
<b>Accessories</b>							
2670-0150	True Union Clamp for 1-1/2 in. Tri Clover						1/1
2672-0150	Gasket for 1-1/2 in. Tri Clover						6/6
712160-0830	83B Replacement Closure for Large Nalgene Bottle or Carboy						2/2
712162-1830	TPE Gasket for 83B Closure						5/5

+ 8250-series products manufactured in our state-of-the-art Suzhou, China facility. All other products manufactured in Rochester, NY.



## Autoclaving Recommendations for Nalgene PC-/PP-based Carboys

- ▶ The recommended autoclaving cycle is 121°C, 1 bar and/or 250°F, 15 psig for 15-20 minutes
- ▶ Avoid stacking carboys or using autoclave baskets with other objects on top
- ▶ Do not secure the openings of the carboy with aluminum foil, blue Steriwrap, gauze, cotton or tape
- ▶ Do not autoclave with the closure—**closure must be completely removed prior to autoclaving with no threads engaged**
- ▶ Wait until the closure and carboy are completely cooled to room temperature before securing closure.
- ▶ If more than 1L of liquid is in the carboy, it may take several hours or more to reach the target sterilization temperature (typically more practical to autoclave the carboy and sterilize liquid by in-line filtration directly into the container)
- ▶ Disposable carboy vent filter (Cat. No. 223-0030) is available featuring a hydrophobic, Teflon™ PTFE membrane, which permits sterile venting on slow exhaust/liquid autoclave cycles for the Nalgene PP and PC carboys up to 50L. This vent filter can be used up to 5 times



# Polypropylene (PP) and Polycarbonate (PC) Sanitary Fitting Carboys

## Perfect for use as supply reservoirs

- Easier to clean than threaded alternatives
- Autoclavable for in-house sterilization
- Round shape for homogeneity during stirring
- Graduations for volume determination at a glance
- PC is crystal clear like glass
- PP convenient shoulder handles for easy carrying



## Recommended Applications

Where cleaning validations are required  
Sterile transfers of product

Cat No	Description	Capacity, L (gal)	Neck Finish	Closure Size, mm	Dimensions		No. per Pk/Cs
					Width/OD, mm (in)	Height with Closure, mm (in)	
2261-0050	PC Carboy	20 (5.3)	3 in. Tri Clover	—	287 (11.3)	498 (19.6)	1/4
2630-0010	PP Carboy	10 (2.6)	3 in. Tri Clover	—	250 (9.8)	353 (13.9)	1/1
2630-0020	PP Carboy	20 (5.3)	3 in. Tri Clover	—	282 (11.1)	496 (19.5)	1/1
2630-0050	PP Carboy	50 (13.2)	3 in. Tri Clover	—	379 (14.9)	545 (21.5)	1/1
2640-0020	PP Carboy with Sanitary Bottom Flange	10 (2.6)	—	83B, 1-1/2 in. Tri Clover	250 (9.8)	389 (15.3)	1/1
2640-0050	PP Carboy with Sanitary Bottom Flange	20 (5.3)	—	83B, 1-1/2 in. Tri Clover	282 (11.1)	526 (20.7)	1/1
2640-0130	PP Carboy with Sanitary Bottom Flange	50 (13.2)	—	83B, 1-1/2 in. Tri Clover	379 (14.9)	678 (26.7)	1/1

## Accessories

2665-0075	End Cap PP Loose 3/4-inch						1/1
2665-0300	End Cap PP Loose 3-inch						1/1
2670-0075	True Union Clamp PVDF Loose 3/4-inch Mini						1/1
2670-0150	True Union Clamp PVDF Loose 1-1/2 inch						1/1
2670-0300	True Union Clamp PVDF Loose 3-inch						1/1
2672-0075	Sanitary Gasket Platinum Cured Silicone 3/4-inch Mini						1/6
2672-0150	Sanitary Gasket Platinum Cured Silicone 1-1/2 inch Tri Clover						1/6
2672-0300	Sanitary Gasket Platinum Cured Silicone 3-inch Tri Clover						1/6
2685-0300	Heavy-Duty Clamp 3 inch Stainless Steel 3-inch						1/1
2688-2075	3-inch Sanitary End Cap PC with two 3/4-inch Sanitary Flanges 3 inch Tri Clover						1/4
2689-2075	3-inch Sanitary End Cap PP with two 3/4-inch Sanitary Flanges 3 inch Tri Clover						1/4

# Regulatory Compliance and Customer Support

**We understand the importance of our customers' critical applications. That's why our containers are manufactured in compliance with rigorous quality systems, ensuring traceability and controls from raw materials through the finished product.**

We make it our mission to support our customers' regulated high-value applications with:

- ISO 13485:2003 and GMP Class I certified manufacturing systems
- Resin and product validation data support
- Lot specific product certificates on demand
- Change control procedures
- Change notification services and support
- Customer onsite audits by appointment

## Manufacturing Certifications

In 2003, the Thermo Fisher Scientific Rochester, New York and Fairport, New York manufacturing facilities achieved ISO 13485 compliance. This upgrade superseded the ISO 9001 system that was in place since May 1995. Both sites are also registered as GMP (Good Manufacturing Practices) facilities for Class I devices (design exempt) with the US Food and Drug Administration. In addition, many of the GMP practices are extended to Nalgene bottle manufacturing, even though the Nalgene bottles themselves are not registered medical devices.

## Resin and Product Validation Data

Most of our resins are DMF-registered by the supplier and meet a number of regulatory specifications including USP Class VI, EP monographs and EU food-contact directives, CONEG, RoHS, CA Prop 65, SARA Title III Sec. 313, 21 CFR pt 177. Most Nalgene resins are free from ADC's, BPA, phthalates, and contact with latex. Compliance statements by catalog number are available by contacting Regulatory Support.

A validation binder containing compliance data and product specifications is available under customer confidentiality agreement. For additional information, contact our Regulatory Support team at [rocrgsupport@thermofisher.com](mailto:rocrgsupport@thermofisher.com)

## Certificates on Demand

Nalgene customers can receive a lot-specific product certificate on demand any time day or night from our website at [www.nalgenelabware.com](http://www.nalgenelabware.com). Click the "Technical Data" dropdown and select "Certificate of Compliance." Enter your contact data and the product lot number and submit your request. A PDF copy of the certificate is delivered instantly for print or download. Or click "Forward Your Request" to email your request to us.

## Change Control Procedures

In accordance with ISO and GMP requirements, changes to manufacturing procedures, packaging and product specifications require methods following specific documented processes for approval and implementation. All changes are documented and traceable.

## Customer Notification Services

Customers can receive electronic notification of changes to product form, fit, function, manufacturing location, tooling and major process changes by registering in our customer change notification database. To register for change notifications for a specific list of Nalgene items, please go to [info.thermoscientific.com/RegisterCustomerNotifications](http://info.thermoscientific.com/RegisterCustomerNotifications)

# Low Density Polyethylene (LDPE)

## High quality option for every-day use

- Leak-proof PP screwtop design (see page 9 for details)
- Convenient shoulder handles for easy carrying and pouring
- Graduations for volume determination at a glance
- Wide-mouth version for easy cleaning, filling and dispensing
- Round for homogeneity during stirring

### Recommended Applications

Light duty applications  
Stirring and storage intermediates



Cat No	Description	Capacity, L (gal)	Closure Size, mm	Dimensions		No. per Pk/Cs
				OD, mm (in)	Height with Closure, mm (in)	
2210-0020	Carboy with Handles	10 (2.6)	83B	250 (9.8)	389 (15.3)	1/6
2210-0040	Carboy with Handles	15 (3.8)	83B	285 (11.2)	429 (16.9)	1/4
2210-0050	Carboy with Handles	20 (5.3)	83B	282 (11.1)	526 (20.7)	1/4
2210-0065	Carboy with Handles	25 (6.5)	83B	287 (11.3)	594 (23.4)	1/4
2210-0130	Carboy with Handles	50 (13.2)	83B	379 (14.9)	668 (26.3)	1/1
2234-0020	Wide-Mouth Carboy with Handles	10 (2.6)	100-415	250 (9.8)	343 (13.5)	1/6
2234-0030	Wide-Mouth Carboy with Handles	15 (3.8)	100-415	286 (11.3)	389 (15.3)	1/6
2234-0050	Wide-Mouth Carboy with Handles	20 (5.3)	100-415	282 (11.1)	483 (19.0)	1/4
<b>Accessories</b>						
712160-0830	83B Replacement Closure for Large Nalgene Bottle or Carboy					2/2



# Quality Control, Testing and Inspection

**Prior to their release to the marketplace, rigorous procedures must be followed.**



## Resin Receiving Inspection

Checks are performed on incoming lots of resin material as noted below. All tests are based on Nalgene container historical data and information supplied by our resin manufacturers.

**Resin Flow:** Melt Flow Indexes are performed on selected lots of incoming resin per ASTM D1238.

**Visuals:** A visual comparison of each lot of resin is performed to assure that there is limited lot-to-lot color variation during manufacturing runs. Granular size and configuration of each lot is also checked to ensure that uniform molding will be accomplished.

## Molding Inspection

Molding inspection is performed in two major steps. Step one is the First Piece Approval stage. Manufacturing must obtain First Piece Approval from Quality Control before any parts can be assigned to stock.

Step two is the critical In-process Inspection. Parts are continually checked at specific intervals during the entire production run. Inspection criteria for the above steps are:

- Physical defects/appearance
- Molding integrity/completeness of threads and sealing ring (closure)
- Standard Nalgene container leak test
- Dimensional checks

## Our Leak-proof Testing Procedures

Containers and closures are tested separately with water. The term “leak-proof” applies to products that meet the following criteria:

- 1]** Carboy/closure systems with closures smaller than 100mm are filled with water, set on their side and air pressure of 2 psig for 2 minutes is applied. The test is successful when no water escapes.
- 2]** Carboy/closure systems with 100mm closures are filled with water, inverted, and are allowed to stand for 15 minutes. The test is successful when no water escapes.

These tests using other liquids may not yield the same results. To ensure safe usage, we recommend testing with your specific container/closure/contained material combination.

**Warning:** Do not use Nalgene carboys or other containers under pressure or vacuum, except those products that are specifically designed, specified and tested for these applications. The application of pressure or vacuum to products not designed for such use may result in failure of the products, damage to property and/or personal injury.











## Resin Codes

<b>ETFE</b>	ETFE (ethylene-tetrafluoroethylene)
<b>FEP</b>	FEP (ethylene-tetrafluoroethylene)
<b>FLPE</b>	flouronated high-density polyethylene
<b>HDPE</b>	high-density polyethylene
<b>LDPE</b>	low-density polyethylene
<b>PC</b>	polycarbonate
<b>PETG</b>	polyethylene terephthalate copolyester
<b>PFA</b>	Teflon <sup>†</sup> PFA (perflouroalkoxy)
<b>PMP</b>	polymethylpentene ("TPX")
<b>PP</b>	polypropylene
<b>PPCO</b>	polypropylene copolymer
<b>TPE</b>	thermoplastic elastomer

## Supporting Resin Information

Refer to the tables on the following pages for resin properties, torque recommendations for our caps and chemical resistance.

### Resin Quick Reference Chart

	Poly-propylene (PP)	Poly-propylene Copolymer (PPCO)	Low Density Polyethylene (LDPE)	High Density Polyethylene (HDPE)	Poly-carbonate (PC)	Poly-methylpentene (PMP)	Polyethylene Terephthalate G Copolyester (PETG)	FEP	PFA	ETFE
<b>High Temperature</b>	135°C	121°C	80°C	120°C	135°C	145°C	70°C	205°C	260°C	150°C
<b>Low Temperature</b>	0°C	-40°C	-100°C	-100°C	-135°C	20°C	-40°C	-270°C	-270°C	-105°C
<b>Autoclavable</b>	Y	Y	N	N	Y	Y	N	Y	Y	Y
<b>Microwaveable</b>	Y	Marginal	Y	N	Marginal	Y	Marginal	Marginal	Y	Y
<b>Dry Heat (Oven)</b>	N	N	N	N	Y	Y	N	Y	Y	Y
<b>Freeze</b>	N	Y	Y	Y	Y	N	Y	Y	Y	Y
<b>Flexibility</b>	Rigid	Moderate	Excellent	Moderate	Rigid	Rigid	Moderate	Excellent	Excellent	Rigid
<b>Clarity</b>	Translucent	Translucent	Translucent	Translucent	Clear	Clear	Clear	Translucent	Nearly Clear	Translucent
<b>Chemical Resistance</b>	Good	Good	Good	Good	Minimal	Good	Minimal	Excellent	Excellent	Excellent
<b>Recycling Symbol</b>	 PP	 PP	 LDPE	 HDPE	 OTHER	 OTHER	 PETE	 OTHER	 OTHER	 OTHER

## Resin Properties

Resin	Max Use Temp <sup>1</sup> (°C)	HDT <sup>2</sup> Temp. (°C)	Brittleness <sup>3</sup> Temp. (°C)	Transparency	Sterilization <sup>5</sup>						Permeability (cc-mil/100 in <sup>2</sup> - 24 hr.-atm)				
					Micro-wave-ability	Auto-claving	Gas	Dry Heat	Radiation	Disinfectants	Specific Gravity	Flexibility	N	O	CO
LDPE	80	45	-100	Translucent	Yes	No	Yes	No	Yes	Yes	0.92	Excellent	180	500	2,700
HDPE	120	65	-100	Translucent	No	No	Yes	No	Yes	Yes	0.95	Rigid	42	185	580
PP	135	107	0	Translucent	Yes	Yes	Yes	No	No	Yes	0.9	Rigid	48	240	800
PPCO	121	90	-40	Translucent	Marginal <sup>4</sup>	Yes	Yes	No	No	Yes	0.9	Moderate	45	200	650
PMP	145	80	20	Clear	Yes	Yes	Yes	Yes	No	Yes	0.83	Rigid	8,000	32,000	115,000
FLPE	120	65	-100	Translucent	No	No	Yes	No	Yes	Yes	0.95	Rigid	42	185	580
ETFE	150	104	-105	Translucent	Yes	Yes	Yes	Yes	Yes	Yes	1.7	Rigid	30	100	250
FEP	205	70	-270	Translucent	Marginal <sup>4</sup>	Yes	Yes	Yes	No	Yes	2.15	Excellent	320	750	2,200
PFA	260	166	-270	Translucent	Yes	Yes	Yes	Yes	No	Yes	2.15	Excellent	291	881	2,260
PETG	70	70	-40	Clear	Marginal <sup>4</sup>	No	Yes	No	Yes	Some	1.27	Moderate	10	25	125
PC	135	138	-135	Clear	Marginal <sup>4</sup>	Yes <sup>6</sup>	Yes	No	Yes	Yes	1.2	Rigid	50	300	1,075
TPE	121	<23	<-50	Opaque	Yes	Yes	Yes	No	Yes	Some	0.93	Excellent	31-145	85-646	900-8,634

## Resin Properties (continued)

Resin	Permeability (cc.-mm/m <sup>2</sup> -24hr.-Bar)			Water Vapor Transmission Rate (g.-mm/m <sup>2</sup> 24 hr.-Bar at 38°C, 90% RH)	Water Adsorption (%)	Non-Cyto-toxicity <sup>7</sup>	Suitability for Food and Bev. Use <sup>8</sup>	Reg Part 21 CFR	Refractive Index	Melting Point Range (°C)	Glass Transition Temperature Range (°C)
	N	O	CO								
LDPE	69.94	154.28	1,049.09	15.5–23.3	<0.01	Yes	Yes <sup>9</sup>	177.1520	1.5400	85 to 125	-25
HDPE	16.32	71.88	225.36	4.6–6.2	<0.01	Yes	Yes <sup>9</sup>	177.1520	1.5100	125 to 138	-25
PP	18.65	93.25	310.84	3.9	<0.02	Yes	Yes	177.1520	1.4735	160 to 176	-20 to -5
PPCO	17.48	77.71	252.56	4.40	<0.02	Yes	Yes	177.1520	1.4735–1.5100	150 to 175	-20
PMP	3,109.42	12,433.68	44,683.32	775	0.01	Yes	No	—	1.4630	235	N/A
FLPE	16.32	71.88	225.36	4.6	<0.01	Yes	Yes <sup>9</sup>	177.1615	1.5100	125–138	-125
ETFE	11.66	38.86	97.14	1.65	0.03	Yes	Yes	177.1550	1.3580	265	N/A
FEP	124.34	291.41	854.82	6.20	<0.01	Yes	Yes	177.1550	1.3380	275	N/A
PFA	118.07	342.31	878.13	2.00	<0.02	Yes	Yes	177.1550	1.3580	302 to 310	N/A
PETG	3.89	9.71	48.57	18.13	0.13	Yes	Yes <sup>10</sup>	177.1315	1.57	265	81
PC	19.43	116.57	417.69	115	0.35	Yes	Yes	177.1580	1.5860	N/A	154
TPE	12.05-56.34	33.03-251	0.70-3,354.76	—	0.05-5.1	Yes	Yes	177.2600	—	N/A	N/A

- Ratings based on 5-minute tests using 600 watts of power on exposed, empty labware. CAUTION: Do not exceed Max. Use Temp., or expose labware to chemicals which heating causes to attack the plastic or be rapidly absorbed.
- Heat Deflection Temperature is the temperature at which a bar deflects 0.01" at 66 psig (ASTM D648). Materials may be used above their heat deflection temperatures in non-stress applications; see maximum use temperature.
- The brittleness temperature is the temperature at which an item made from the resin may break or crack if dropped. This is not the lowest use temperature if care is exercised in use and handling.
- Plastic will absorb heat.
- STERILIZATION
  - Autoclaving (121°C, 15 psig for 20 minutes) – clean and rinse items with distilled water before autoclaving. (Always completely disengage thread before autoclaving.) Certain chemicals which have no appreciable effect on resins at room temperature may cause deterioration at autoclaving temperatures unless removed with distilled water beforehand.
  - Gas – Ethylene oxide, formaldehyde, hydrogen peroxide
  - Dry Heat (160°C, 120 minutes)
  - Disinfectants – benzalkonium chloride, formalin/formaldehyde, ethanol, etc.
  - Radiation – gamma irradiation at 25 kGy (2.5 MRad) with unstabilized plastic
- Autoclaving reduces mechanical strength. Do not use PC vessels for vacuum applications if they have been autoclaved.

- "Yes" indicates the resin has been determined to be non-cytotoxic, based on USP and ASTM biocompatibility testing standards utilizing an MEM elution technique on a WI38 human diploid lung cell line.
- Resins meet requirements of CFR21 section of Food Additives Amendment of the Federal Food and Drug Act. End users are responsible for validation of compliance for specific containers used in conjunction with their particular packaging applications.
- Acceptable for:
  - Nonacid, aqueous products; may contain salt, sugar or both (pH above 5.0).
  - Dairy products and modifications; oil-in-water emulsions, high or low fat.
  - Moist bakery products with surface containing no free fat or oil.
  - Dry solids with the surfaces containing no free fat or oil (no end-test required) and under all conditions as described in Table 2 of FDA Regulation 177.1520 except condition A—high temperature sterilization (e.g. over 100°C/212°F).
- Acceptable for:
  - Alcoholic foods containing not more than 15% (by volume) alcohol; fill and storage temperature not to exceed 49°C (120°F).
  - Non-alcoholic foods of hot fill to not exceed 82°C (180°F) and 49°C (120°F) in storage.
  - Not suitable for carbonated beverages or beer or packaging food requiring thermal processing.



# Chemical Resistance Classification

Refer to the data below to ensure proper carboy selection for your specific applications

## Chemical Resistance Classification

	ETFE	FLPE	HDPE	LDPE	PC	PETG	FEP/PFA	PMP	PP/PPCO	TPE**
Acids, dilute or weak	E	E	E	E	E	G	E	E	E	G
Acids *strong and concentrated	E	G	G	G	N	N	E	E	G	F
Alcohols, aliphatic	E	E	E	E	G	G	E	E	E	E
Aldehydes	E	G	G	G	F	G	E	G	G	G
Bases/Alkali	E	F	E	E	N	N	E	E	E	F
Esters	G	G	G	G	N	F	E	E	G	N
Hydrocarbons, aliphatic	E	E	G	F	G	G	E	G	G	E
Hydrocarbons, aromatic	G	E	N	N	N	N	E	N	N	N
Hydrocarbons, halogenated	G	G	N	N	N	N	E	N	N	F
Ketones, aromatic	G	G	N	N	N	N	E	F	N	N
Oxidizing Agents, strong	E	F	F	F	F	F	E	G	F	N

\*Except for oxidizing acids: for oxidizing acids, see "Oxidizing Agents, strong."

\*\* TPE gaskets.

## Chemical Resistance Classification

**E:** 30 days of constant exposure causes no damage. Plastic may even tolerate for years.

**G:** Little or no damage after 30 days of constant exposure to the reagent.

**F:** Some effect after 7 days of constant exposure to the reagent. Depending on the plastic, the effect may be crazing, cracking, loss of strength or discoloration. Solvents may cause softening, swelling and permeation losses with LDPE, HDPE, PP, PPCO and PMP. The solvent effects on these five resins are normally reversible; the part will usually return to its normal condition after evaporation.

**N:** Not recommended for continuous use. Immediate damage may occur. Depending on the plastic, the effect will be a more severe crazing, cracking, loss of strength, discoloration, deformation, dissolution or permeation loss.

**This information is only a summary. To access our chemical resistance database, go to: [www.thermoscientific.com/chemicalresistance](http://www.thermoscientific.com/chemicalresistance)**

# Torque Recommendations

Torque must be properly applied in measured amounts to Nalgene closures to assure leak-proof sealing. To maintain the closure/carboy seal and minimize back-off during shipment, Nalgene closures should be tightly applied using the guidelines provided.

**NOTE:** Carboy and closure threads must be dry when torque is applied to the system.

Because different applications will require different torques for the same closure/bottle system, it is recommended that users determine these values on their own filling and capping lines. With automatic capping machines, application torque must be correlated to removal torque using torque wrenches.<sup>1</sup>

## Recommended application torques for Nalgene closures

Closure Size, mm	Minimum Torque		Maximum Torque <sup>2</sup>	
	in.-lb.	1 cm-kg	in.-lb.	1 cm-kg
11	2	3	3	4
13-415	5	6	7	8
20-415	10	11	14	16
24-415	12	13	17	19
28-415	16	18	22	25
33-415	20	23	28	32
38*	27	31	33	38
38-415	22	25	31	38
38-430	27	31	33	38
43-415	28	32	39	44
48-415	30	34	42	48
48*	30	34	42	48
53-415	33	38	46	52
53B	38	43	53	60
63-415	40	46	56	64
70	44	50	62	71
83B	60	69	84	96

<sup>1</sup>For details, refer to the Handbook of Package Engineering, Third Edition by Joseph F. Hanlon

<sup>2</sup>This number should not be exceeded. It is strongly recommended that users verify these torque numbers, based on their applications. For more information, contact technical support

\* Biotainer™ container closures



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