thermo scientific



Nalgene Biotainer bottles and carboys

Safe containment of your critical products

ThermoFisher SCIENTIFIC


900
300
700
500
400
200
100

Specify Nalgene Biotainer bottles and carboys and focus on your process, not the container

Thermo Scientific™ Nalgene™ Biotainer™ bottles and carboys are specifically designed to ensure the integrity of your valuable contents and meet demanding biotechnology requirements, including prolonged storage of pH-sensitive materials, freezing of contents, and storage and transport of harsher materials.

Eliminate the cost of cleaning, sterilizing, and associated validations compared to bottles designed for reuse.

- Sterile and ready to use
- Guaranteed leakproof*
- Extensive validation documentation
- Customized fluid transfer options available

Experience and reliability

- Thirty years of molding experience help ensure a reliable partner with assurance of supply for your critical storage applications
- QC tests performed at startup and specific manufacturing intervals include container and closure leak testing as well as appearance and critical dimension tolerances; 100% in-line leak testing confirms container integrity

Flexibility and ease of use

- Products are sterile and available in a wide variety of sizes from 5 mL to 20 L to accommodate QC sampling, validation, and in-process use such as media or product storage
- Available in three resins:
  - **Polycarbonate (PC)**—robust for temperatures down to –100°C
  - **Polyethylene terephthalate (PETG)**—crystal clear; low gas permeation for pH-sensitive materials
  - **High-density polyethylene (HDPE)**—high chemical resistance for storage of harsher material; more information on chemical resistance can be found at **thermofisher.com/chemicalresistance**
- Leakproof closure and bottle system with virtually strip-proof threads helps reduce loss of sample during handling, storage, and transport
- The product number, description, sterilization lot, and expiration date are clearly printed on inner packaging labels
- Clear graduations enable rapid volume determination, and molded-in grips or handles ease bottle handling even with gloves and when frozen
- Optimal square footprint of most containers maximizes storage space on shelves or in incubators, freezers, or refrigerators



Specifications

Shelf life	
Expiration	5 years
Certifications or compliance	
Visual inspection	Yes
Endotoxin requirement, per USP <85>	<0.5 EU/mL
Certified sterile (sterility assurance level of 10^{-6})	Yes
Nonpyrogenic	Yes
Compendial extraction testing	
Noncytotoxic	Yes
Nonhemolytic	ISO 10993-3
USP Class VI compliant	Yes
USP <661> physicochemical tests compliant	Yes, Rev. 37 Physicochemical
Animal components: BSE and TSE regulatory statements	Animal-derived components in white colorant of closure
EMEA 410/01 compliant	Yes
Melamine	No melamine
Extractable studies	Yes



Proven solution for frozen applications

Nalgene PC Biotainer Bottles and Carboys

The robustness and impact resistance of PC at cold temperatures make sterile Thermo Scientific™ Nalgene™ PC Biotainer™ Bottles and Carboys ideal for freezing all of your high-value products.

For configurations as part of closed systems for liquid transfer, containers larger than 1 L fit Nalgene 48 mm, 2- and 3-ported closures for tubing and other accessories.

- White, silicone-lined, radiation-stable polypropylene (PP) closure
- Graduations printed on bottles and molded into containers over 5 L
- Recommended temperature range of –100°C to 100°C
- Validation vials available in 5 mL and 20 mL sizes



Ordering information

Capacity	Handle	Closure size (mm)	Shape, diameter (mm) x height (mm)	Product labels	Quantity per pack/case	Cat. No.
5 mL	NA	20	Round, 22 x 47	NA	100/500	3500-05
20 mL	NA	20	Round, 30 x 69	NA	100/500	3500-20
125 mL	Molded-in grips	38	Square, 52 x 105	Lot No. printed on bottles	5/50	3030-42
1 L	Molded-in grips	48	Square, 98 x 201	Lot No. printed on bottles	5/35	3120-42
2 L	Molded-in grips	48	Square, 116 x 265	Lot No. printed on bottles	5/20	3233-42
5 L	Attached polyethylene (PE) handle	48	Square, 166 x 299	Cat. No., Lot No., description, serial number, and expiration date labeled on bottles	1/6	3405-16
5 L	NA	48	Square, 166 x 299	Cat. No., Lot No., description, serial number, and expiration date labeled on bottles	1/6	3405-42
10 L	Attached PE handle	48	Square, 255 x 337	Cat. No., Lot No., description, serial number, and expiration date labeled on bottles	1/2	3410-08
10 L	NA	48	Square, 255 x 337	Cat. No., Lot No., description, serial number, and expiration date labeled on bottles	1/2	3410-42
20 L	NA	48	Square, 255 x 493	Cat. No., Lot No., description, serial number, and expiration date labeled on bottles	1/3	3423-42

Robust gas-barrier properties

Nalgene PETG Biotainer Bottles and Carboys

The crystal-clear Thermo Scientific™ Nalgene™ PETG Biotainer™ Bottles and Carboys offer low permeability to gases such as O_2 and H_2O_2 and are suitable for storage in conditions from –70°C to 70°C.

For configurations as part of closed systems for liquid transfer, containers larger than 1 L fit Nalgene 48 mm, 2- and 3-ported closures for tubing and other accessories.

- White, low-density polyethylene (LDPE)-lined, radiation-stable PP closure
- Graduations printed on bottles



Ordering information

Capacity	Handle	Closure size (mm)	Shape, diameter (mm) x height (mm)	Product labels	Quantity per pack/case	Cat. No.
125 mL	Molded-in grips	38	Square, 52 x 105	Lot No. printed on bottles	5/100	3025-42
500 mL	Molded-in grips	38	Square, 77 x 176	Lot No. printed on bottles	5/70	3005-42
500 mL	Molded-in grips	38	Square, 77 x 176	Lot No. printed on bottles	35/70	3005-70
1 L	Molded-in grips	48	Square, 98 x 201	Lot No. printed on bottles	5/35	3110-42
1 L	Molded-in grips	48	Square, 98 x 201	Lot No. printed on bottles	35/35	3110-35
2 L	Molded-in grips	48	Square, 116 x 265	Lot No. printed on bottles	20/20	3230-20
2 L	Molded-in grips	48	Square, 116 x 265	Lot No. printed on bottles	5/20	3230-42
5 L	Attached PE handle	48	Square, 166 x 299	Cat. No., Lot No., description, serial number, and expiration date labeled on bottles	1/6	3415-16
5 L	NA	48	Square, 166 x 299	Cat. No., Lot No., description, serial number, and expiration date labeled on bottles	1/6	3415-42

When only the cleanest will do

Certified-clean containers with low levels of particulates and endotoxins help to reduce risks of contamination, adhering to USP <788> guidelines. If you need the cleanest possible containers available, consider Thermo Scientific™ Nalgene™ Certified Platinum Clean containers, which are validated to not exceed one third of the particulate limits per USP <788> guidelines. Contact your sales representative to learn more.

Excellent chemical resistance

Nalgene HDPE Biotainer Bottles

Sterile, ready-to-use Thermo Scientific™ Nalgene™ HDPE Biotainer™ Bottles offer excellent chemical resistance and support storage conditions of –100°C to 120°C. The wide range of chemical compatibilities makes them a great option for storage of harsher materials.

- White, LDPE-lined, radiation-stable PP closure
- Graduations printed on bottles
- Available with tamper-evident band (Cat. No. 3750-24)



Ordering information

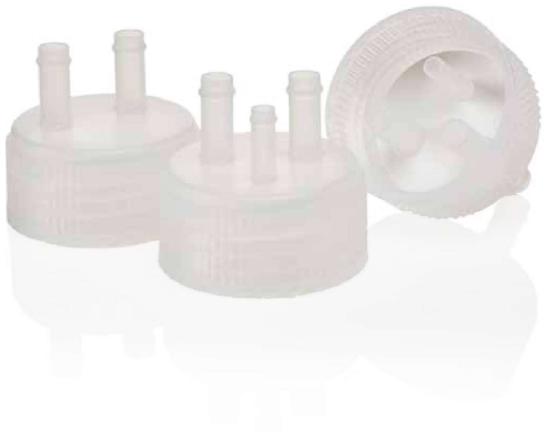
Capacity	Handle	Closure size (mm)	Shape, diameter (mm) x height (mm)	Product labels	Quantity per pack/case	Cat. No.
4 L	Molded-in handle	38	Square, 143 x 299	Lot No. printed on bottles	8/24	3750-24
4 L	Molded-in handle	38	Square, 143 x 299	Lot No. printed on bottles	24/24	3751-24
4 L	Molded-in handle	38	Square, 143 x 299	Lot No. printed on bottles	8/24	3751-42



Ported closures for Nalgene Biotainer bottles and carboys

Thermo Scientific™ Nalgene™ 2- and 3-ported closures for Biotainer™ bottles and carboys are designed to aseptically handle solutions in liquid transfer applications.

- Fits 1–20 L Nalgene Biotainer bottles and carboys made of PC or PETG
- Made with the same materials as our Nalgene Biotainer bottle and carboy closures to enable easier validation in fluid transfer processes and use down to –40°C
- Tubulation ports are present on top of as well as inside the cap
- Leakproof closures with ultrasonically welded liners help reduce product loss during handling, storage, and transport
- Noncytotoxic, nonpyrogenic, nonmutagenic, and animal-derived component free (ADCF) to assure stored material integrity
- Manufactured in an ISO 14644-1 Class VII clean room and double bagged in an ISO Class IV clean room



Ordering information

No. of ports	Port ID	Closure size (mm)	Closure material	Min/max torque values (in.-lb.)	Quantity per pack/case	Cat. No.
3	Two 1/4 in. (6.4 mm) and one 3/16 in. (4.8 mm)	48	PP with sonically welded silicone liner	30/42	4/4	2560-0489
2	Two 1/4 in. (6.4 mm)	48	PP with sonically welded silicone liner	30/42	4/4	2560-0490

Sterile polypropylene (PP) replacement closures

Protect the contents of your Nalgene Biotainer bottles and carboys. Thermo Scientific™ Nalgene™ Sterile PP Biotainer™ Replacement Closures are for 1, 2, 5, 10, and 20 L Nalgene PC Biotainer Bottles and Carboys.

Ordering information

Closure size (mm)	Closure material	Quantity per case/pack	Cat. No.
48	PP with sonically welded silicone liner	300/300	362515-0480

Seal integrity

The integrity of a container's seal is critical for preventing loss of contents or contamination from outside sources. Several factors affect the seal integrity of a closure; among those is the amount of torque applied to close the container. The following table shows the recommended torque values for Nalgene Biotainer bottles and carboys.

Ordering information

Capacity	Closure size (mm)	Torque values (in.-lb.) Minimum	Maximum	Container Cat. No.
PC				
5 mL	20	–	–	3500-05
20 mL	20	–	–	3500-20
125 mL	38	27	33	3030-42
1 L	48	30	42	3120-42
2 L	48	30	42	3233-42
5 L	48	30	42	3405-16
5 L	48	30	42	3405-42
10 L	48	30	42	3410-08
10 L	48	30	42	3410-42
20 L	48	30	42	3423-42
PETG				
125 mL	38	27	33	3025-42
500 mL	38	27	33	3005-42
500 mL	38	27	33	3005-70
1 L	48	30	42	3110-42
1 L	48	30	42	3110-35
2 L	48	30	42	3230-20
2 L	48	30	42	3230-42
5 L	48	30	42	3415-16
5 L	48	30	42	3415-42
HDPE				
4 L	38	27	33	3750-24
4 L	38	27	33	3751-24
4 L	38	27	33	3751-42

This number should not be exceeded. It is strongly recommended that users verify these torque numbers, based on their applications. For more information, contact **technicalsupport@thermofisher.com**.

For further information on the seal integrity of Nalgene Biotainer closures, contact your sales specialist for a copy of our application note that examines the effects of time, temperature, and closure application torque on the integrity of the closure seal and the propensity of the seal to loosen under certain conditions.


2000
1800
1600
1400
1200
1000
800
600
400
200
1012003
(MLs) 500
400
300
200
100

Additional resources

Certificates: Resins are Drug Master File (DMF) registered to meet regulatory specifications, and Certificates of Compliance (CoC) are available on product pages at **thermofisher.com**.

Validation support: Detailed validation binders** and forced extraction studies are available upon request from **rocregsupport@thermofisher.com**.

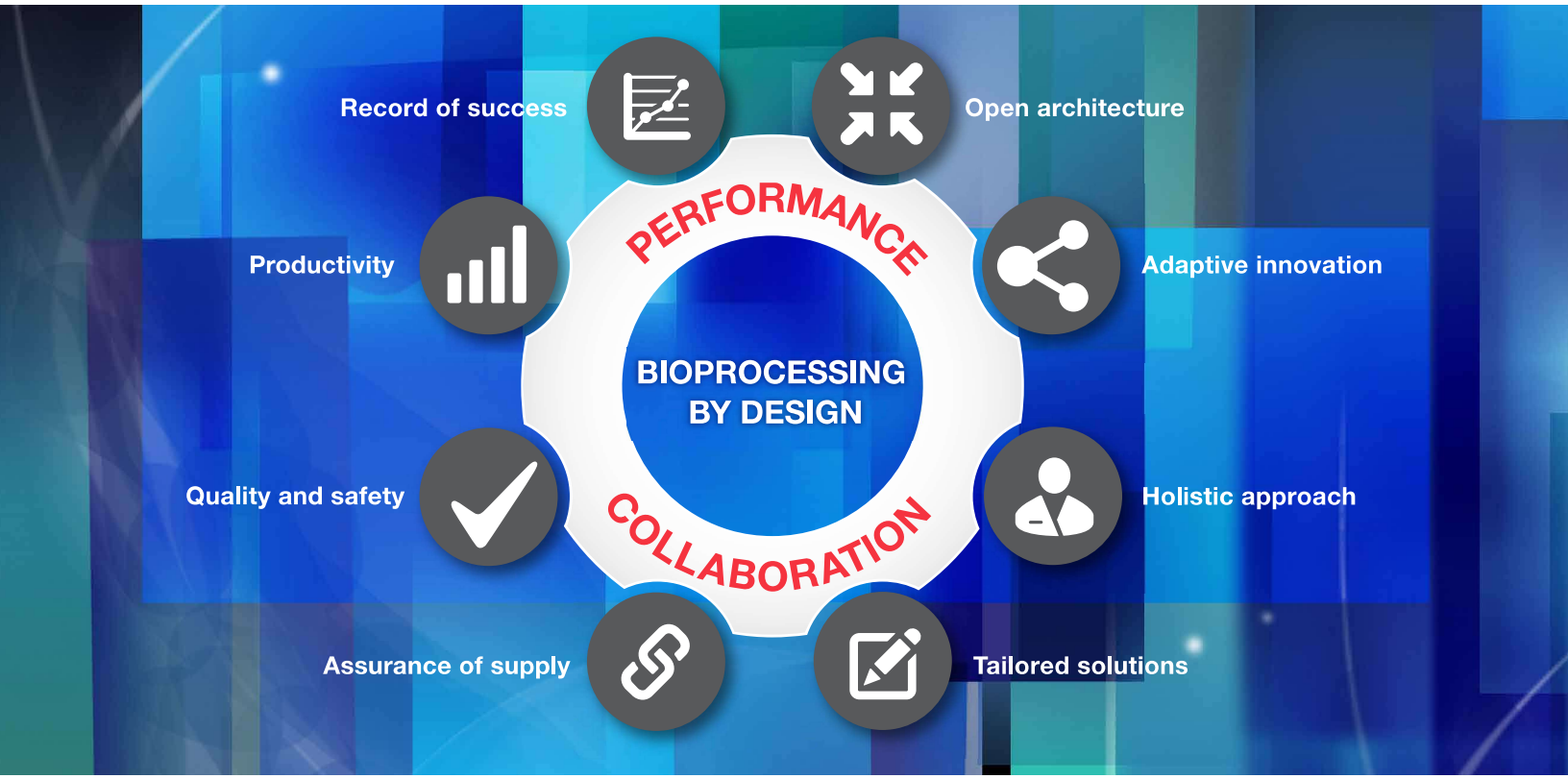
Change notifications: Compliance with ISO 13485:2003 and cGMP requirements means that changes to manufacturing procedures, packaging, and product specifications are all documented and traceable. To receive notifications of any changes, register at **thermofisher.com/registercustomernotifications**.



* The term "leakproof" applies to Nalgene products that meet the following criteria: (1) for bottle/flask/funnel closure systems with closures smaller than 100 mm, after they are filled with water, inverted, and subjected to air pressure of 2 psig for 2 minutes, no water escapes; (2) for bottle/flask/funnel closure systems with closures larger than 100 mm, after they are filled with water and inverted for 15 minutes, no water escapes. Note: These tests, using other liquids, may not yield the same results. To ensure safe usage, customers are advised to test Nalgene bottles and closures under the conditions of their planned applications. Nalgene products are leakproof at ambient temperature and pressure when used with their Nalgene closures.

** Documentation is available to support the product validation process. This confidential information can be requested at: **rocregsupport@thermofisher.com**. Following a request submission, a confidentiality agreement will be forwarded to you for execution.

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Bioprocessing by Design

Driving performance through collaboration

To meet the increasing demand for biologics worldwide, you need to expect more from suppliers. It isn't just about the products we deliver, but how we do business together.

With a collaborative approach that is grounded in our technical knowledge, we work with you to achieve optimal bioprocessing outcomes. Committed to identifying the technologies and services that address your needs, from drug development through large-scale commercial production, we provide integrated and tailored solutions that improve the overall biomanufacturing experience. If a solution doesn't exist, we'll build it—together.

And while we are flexible in our approach, we are uncompromising in our pursuit of performance. Through technical engagement, innovative product design, and strategic sourcing programs, we deliver productivity, quality, and assurance of supply so that you can have complete confidence in the efficiency and speed of your biologics development and manufacturing processes.

That's our commitment to you, and it's what we call Bioprocessing by Design.

Find out more at **thermofisher.com/biotainer**

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