DATA SHEET

Nalgene containers developed specifically for the risk-averse

Clean containers that meet the demands of your workflow and the regulatory bodies that govern it

Making sure the equipment and materials used in critical environments meet the demanding standards of cleanliness can be a challenging process. Reduce the risk of failing to meet USP <788> requirements by using the cleanest validated containers on the market.

Packaging in the right configuration

The Thermo Scientific[™] Nalgene[™] multi-tiered portfolio provides bioproduction facilities with a variety of highquality, sterile storage and transport solutions. This enables you to choose the appropriate product necessary to suit your application—through the step-down process and into your clean room.

| Tier | PETG | PC | HDPE |
|--------------------------|------|----|------|
| Standard clean | • | ٠ | • |
| Certified clean | ٠ | ٠ | |
| Platinum certified clean | • | ٠ | • |

Key features

- Multiple tiers
 - Platinum certified clean containers are certified to contain less than 1/3 of the allowable particulate limits specified in USP <788>
 - Certified clean containers meet USP <788> low particulate requirements
- Multiple resins available
 - Polycarbonate (PC)
 - Polyethylene terephthalate (PETG)
 - High-density polyethylene (HDPE)
- Sterile, ready-to-use products with robust triple-layer packaging for your step-down process
 - 2 heat-sealed bags create dual sterile barriers
 - 1 carton liner
 - Double-walled cartons
 - Improved labeling
- Produced in clean room (ISO class 7)
- Certified leakproof* to protect valuable contents

* Our guarantee for a leakproof seal is subject to our standard product warranty, as set forth in the Thermo Fisher Scientific Terms and Conditions of Sale. Our products are leakproof at ambient temperature and pressure when used with their corresponding closures. However, to ensure safe usage, customers are advised to test our containers and closures under conditions of their planned applications. Please contact **technicalsupport@thermofisher.com** if you need additional information about our products.





| | Certified clean | Platinum certified clean |
|--|---|---|
| Packaging | | |
| Triple-layer outer packaging | Container(s) in a labeled heat-sealed b heat-sealed bag. Multiple packs are g in a carton, and closed with a cable ti | athered in a carton liner bag, placed |
| Labeling | Visible through each packaging layer | |
| Double-walled cartons | Yes | Yes |
| Shelf life | | |
| Expiration (years) | 5 | 5* |
| Certifications/compliance | | |
| Visual inspection | Yes | Yes |
| Particle specification | USP <788> | Below 1/3 of USP <788> limits |
| Endotoxin requirement (per USP <85>) | <0.5 EU/mL | <0.25 EU/mL |
| Certified sterile (SAL of 10 ⁻⁶)* | Yes | Yes |
| Nonpyrogenic | Yes | Yes |
| Compendial and extraction testing | | |
| Noncytotoxic | Yes | Yes |
| Nonhemolytic | ISO 10993-3 | ISO 10993-3 |
| USP Class VI compliant/certificate | Yes | Yes |
| USP <661> physicochemical tests-compliant | Yes, rev 37 physicochemical | Yes, rev 37 physicochemical |
| Animal components according to BSE/TSE** regulatory statements | Certain SKUs contain animal-derived components; uncolored closure | Certain SKUs contain animal- derived components; white closure |
| EMEA 410/01-compliant | Yes | Yes |
| Melamine | No | No |
| Validation reports available | Yes | Yes |

* Certain products are currently 2 years and undergoing validation to extend shelf life. ** SAL: sterility assurance level; BSE/TSE: bovine spongiform encephalopathy/transmissible spongiform encephalopathies.

PETG

PETG containers have robust gas-barrier properties and offer low permeability to gases such as O_2 and H_2O_2 .

- Suitable for storage in conditions from -70°C to 70°C
- White, low-density polyethylene (LDPE)-lined, radiationstable polypropylene (PP) closure

Ordering information

| Thermo Scientific [™] Nalgene [™] PETG Certified Clean Biotainer [™] Bottles | | | | | | | |
|---|--------------|---------------------|---------------------|------------------------|-----------|--|--|
| Volume | Closure size | Outer diameter (OD) | Height with closure | Quantity per pack/case | Cat. No. | | |
| 125 mL | 38 mm | 52 mm | 105 mm | 5/100 | 76397-886 | | |
| 500 mL | 38 mm | 77 mm | 176 mm | 5/70 | 76397-888 | | |
| 1,000 mL | 48 mm | 98 mm | 201 mm | 5/35 | 76397-890 | | |
| 2,000 mL | 48 mm | 116 mm | 265 mm | 20/20 | 76397-892 | | |
| 2,000 mL | 48 mm | 116 mm | 265 mm | 5/20 | 76397-894 | | |
| 5,000 mL | 48 mm | 166 mm | 299 mm | 1/6 | 76397-894 | | |
| 5,000 mL | 48 mm | 166 mm | 299 mm | 1/6 | 76397-898 | | |

* With polyethylene handle.

Thermo Scientific[™] Nalgene[™] Square PETG Platinum Certified Clean Biotainer Bottles

| Volume | Closure size | Outer diameter (OD) | Height with closure | Quantity per pack/case | Cat. No. |
|----------|--------------|---------------------|---------------------|------------------------|-----------|
| 125 mL | 38 mm | 52 mm | 105 mm | 5/100 | 76412-170 |
| 500 mL | 38 mm | 77 mm | 176 mm | 5/70 | 76412-168 |
| 1,000 mL | 48 mm | 98 mm | 201 mm | 5/35 | 76412-172 |
| 2,000 mL | 48 mm | 116 mm | 265 mm | 5/20 | 76412-174 |
| 5,000 mL | 48 mm | 166 mm | 299 mm | 1/6 | 76412-176 |

| Thermo Scientific [™] Nalgene [™] Square PETG Certified Clean Media Bottles | | | | | | | |
|---|--------------|---------------------|---------------------|------------------------|-----------|--|--|
| Volume | Closure size | Outer diameter (OD) | Height with closure | Quantity per pack/case | Cat. No. | | |
| 30 mL | 20 mm | 38 mm | 64 mm | 6/72 | 89093-194 | | |
| 60 mL | 24 mm | 41 mm | 82 mm | 6/72 | 89093-196 | | |
| 125 mL | 38-430 | 52 mm | 108 mm | 6/48 | 89093-198 | | |
| 250 mL | 38-430 | 59 mm | 144 mm | 6/48 | 89093-200 | | |
| 500 mL | 38-430 | 73 mm | 178 mm | 4/24 | 89093-202 | | |
| 1,000 mL | 38-430 | 92 mm | 219 mm | 2/24 | 89093-204 | | |
| 2,000 mL | 53B | 116 mm | 271 mm | 1/12 | 89093-206 | | |

| Thermo Scientific [™] Nalgene [™] Square PETG Platinum Certified Clean Media Bottles | | | | | | |
|--|--------------|---------------------|---------------------|------------------------|-----------|--|
| Volume | Closure size | Outer diameter (OD) | Height with closure | Quantity per pack/case | Cat. No. | |
| 5 mL | 20 mm | 22 mm | 46 mm | 52/416 | 76397-906 | |
| 20 mL | 20 mm | 30 mm | 65 mm | 84/504 | 76397-908 | |
| 30 mL | 20 mm | 38 mm | 64 mm | 7/70 | 76397-864 | |
| 60 mL | 24 mm | 41 mm | 82 mm | 6/72 | 76397-866 | |
| 125 mL | 38-430 mm | 54 mm | 110 mm | 5/50 | 76397-868 | |
| 250 mL | 38-430 mm | 59 mm | 144 mm | 12/48 | 76397-870 | |
| 500 mL | 38-430 mm | 74 mm | 177 mm | 5/70 | 76397-918 | |
| 1,000 mL | 38-430 mm | 92 mm | 219 mm | 5/35 | 76397-914 | |
| 2,000 mL | 53B | 116 mm | 271 mm | 5/20 | 76397-916 | |

| Thermo Scientific [™] Nalgene [™] PETG Certified Clean Validation Bottle | | | | | | | |
|--|-----------|----------|---------|--------|-----------|--|--|
| VolumeClosure sizeOuter diameter (OD)Height with closureQuantity per pack/caseCat. No. | | | | | Cat. No. | | |
| 5 mL | 20-415 mm | 22.25 mm | 45.9 mm | 52/416 | 76397-858 | | |
| 20 mL | 20-415 mm | 29.72 mm | 64.5 mm | 84/504 | 76411-626 | | |

PC

The robustness and impact resistance of PC at cold temperatures make PC bottles and carboys ideal for freezing all of your high-value products.

- White, silicone-lined, radiation-stable PP closure
- Recommended temperature range of -100°C to 100°C
- Validation vials available in 5 mL and 20 mL sizes

Ordering information

| Thermo Scientific [™] Nalgene [™] PC Certified Clean Biotainer [™] Bottles and Carboys | | | | | | |
|---|--------------|---------------------|---------------------|------------------------|-----------|--|
| Volume | Closure size | Outer diameter (OD) | Height with closure | Quantity per pack/case | Cat. No. | |
| 125 mL | 38 mm | 52 mm | 105 mm | 5/50 | 76397-900 | |
| 1,000 mL | 48 mm | 98 mm | 201 mm | 5/35 | 76397-902 | |
| 2,000 mL | 38 mm | 116 mm | 265 mm | 5/20 | 76397-904 | |
| 5,000 mL | 38 mm | 166 mm | 299 mm | 1/6 | 75832-264 | |
| 5,000 mL | 48 mm | 166 mm | 299 mm | 1/2 | 75832-266 | |
| 10,000 mL | 48 mm | 255 mm | 337 mm | 1/2 | 75832-268 | |
| 10,000 mL | 48 mm | 255 mm | 337 mm | 1/2 | 75832-270 | |
| 20,000 mL | 48 mm | 255 mm | 495 mm | 1/3 | 75832-272 | |

* With attached handle.

| Thermo Scientific [™] Nalgene [™] PC Platinum Clean Biotainer [™] Bottles and Carboys | | | | | | | |
|--|--------------|---------------------|---------------------|------------------------|-----------|--|--|
| Volume | Closure size | Outer diameter (OD) | Height with closure | Quantity per pack/case | Cat. No. | | |
| 5 mL | 20 mm | 22 mm | 46 mm | 52/416 | 76397-910 | | |
| 20 mL | 20 mm | 30 mm | 69 mm | 84/504 | 76397-912 | | |
| 125 mL | 38 mm | 52 mm | 105 mm | 5/50 | 76397-872 | | |
| 1,000 mL | 48 mm | 98 mm | 201 mm | 5/35 | 76397-874 | | |
| 2,000 mL | 38 mm | 116 mm | 265 mm | 5/20 | 76397-876 | | |
| 10,000 mL | 48 mm | 255 mm | 337 mm | 1/2 | 76397-878 | | |

| Thermo Scientific [™] Nalgene [™] PC Certified Clean Validation Bottle | | | | | | |
|--|-----------|---------|---------|--------|-----------|--|
| VolumeClosure sizeOuter diameter (OD)Height with closureQuantity per pack/caseCat. No. | | | | | | |
| 5 mL | 20-400 mm | 22.4 mm | 46.7 mm | 52/416 | 76397-860 | |
| 20 mL | 20-400 mm | 29.7 mm | 65.3 mm | 84/504 | 76397-862 | |

HDPE

HDPE containers offer excellent chemical resistance, and the wide range of chemical compatibilities makes them a great option for storage of harsh materials.

- Support storage conditions of -100°C to 120°C
- LDPE-lined, radiation-stable PP closure (sizes 10 L and above with white PP closures)

Ordering information

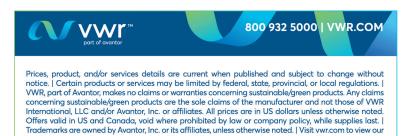
| Thermo Scientific [™] Nalgene [™] Platinum Certified Clean HDPE Bottles and Carboys | | | | | | | | |
|---|--------|--------------|----------------------|---------------------|-------------------|-----------|--|--|
| Description | Volume | Closure size | Optical density (OD) | Height with closure | No. per pack/case | Cat. No. | | |
| | 30 mL | 20-415 | 34.3 mm | 61 mm | 12/72 | 75834-418 | | |
| Narrow- | 250 mL | 24-415 | 61 mm | 133 mm | 12/72 | 75834-416 | | |
| mouth bottle | 500 mL | 28-415 | 72.6 mm | 170.4 mm | 12/48 | 75834-412 | | |
| | 1 L | 38-430 | 91.4 mm | 215.9 mm | 6/24 | 75834-408 | | |
| \A/' I II | 250 mL | 43-415 | 61 mm | 99.3 mm | 12/72 | 75834-414 | | |
| Wide-mouth bottle | 500 mL | 53-415 | 72.6 mm | 168.2 mm | 12/48 | 75834-410 | | |
| bottio | 1 L | 63-415 | 91.44 mm | 199.2 mm | 6/24 | 75834-406 | | |
| Carboy with integrated | 10 L | | 250.2 mm | 389 mm | 1/6 | 75835-976 | | |
| | 20 L | 83B | 284.2 mm | 501.7 mm | 1/4 | 75835-974 | | |
| handles | 33 L | | 381 mm | 546 mm | 1/1 | 75835-972 | | |

thermo scientific

Manufactured, tested, and supported for critical applications

- Forced extraction studies and validation binders* can be requested by emailing our technical support staff at rocregsupport@thermofisher.com.
- Certificates on demand: Customers can obtain a lot-specific Nalgene product certificate on demand at any time from our website. Enter the lot number in the field at the bottom of each product webpage, and a PDF of the certificate is instantly available for print or download.
- Sign up for notifications: Receive electronic notification of changes to product form, fit, function, manufacturing location, and tooling as well as major process changes by registering in our customer change notification database. To register for change notifications for a specific list of Nalgene products, go to **thermofisher.com/registercustomernotifications**.

* Forced extraction studies and validation binders from Thermo Fisher Scientific are provided, where available, under a confidentiality agreement to assist customers in product selection. Customers are responsible for determining which studies are recommended for its specific applications. Forced extraction studies and validation binders may be requested by contacting us at **rocregsupport@thermofisher.com**.



privacy policy, trademark owners, and additional disclaimers. © 2020 Avantor, Inc. All rights reserved.



For Research Use or Further Manufacturing. Not for diagnostic use or direct administration into humans or animals. © 2020 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified.

