

## Thermo Scientific Nalgene Certified Platinum Clean HDPE Bottles and Carboys

What do ultra-clean bottles and carboys deliver to my biopharmaceutical and vaccine production?

### Low particulates, sterility, low endotoxins and more help maintain product integrity

- Inspection procedures throughout manufacturing include leak testing, dimensional testing, multiple visual inspections for particulates and release testing to ensure the container meets all specifications
- Specially-designed automated washers use only USP Purified Water, including USP WFI for the final rinse, so there are no added detergents or chemicals
- All container/closure systems certified leakproof\* to protect precious contents
- Certified low endotoxin (0.25 EU/mL) according to USP <85> to limit pyrogens
- Class 100 (ISO Class 5) cleanroom handling following washing and drying, including Class 10 (ISO Class 4) hoods for packaging
- Robust, HDPE can be used from -100°C to 65°C, allowing for both heated mixing and frozen storage or shipment. It is recommended to always test in actual use conditions, as results may vary depending upon application.

### Ultra-clean containers in bioproduction

Sterile bottles and carboys, free from added interfering chemicals and low in particulates, are required to maintain both cleanroom as well as product integrity.



### Key Features

- Water-washed containers that reduce particle load contribution
- Certified to contain less than 1/3 of the allowable particulates limits specified in USP <788>
- Sterile products ready-to-use with robust triple-layer packaging for cleanroom use
- Products can be supplied with forced extraction studies, validation binders and certificates

## Manufactured, Tested and Supported for Critical Applications

- Products are certified sterile and contain below 1/3 of the particulate matter limits specified in USP <788>, low endotoxin according to USP <85> and in heat-sealed packaging ready for cleanroom use
- All packs are double heat-sealed, packs placed in carton liner twisted and tape/tie sealed for cleanroom use
- High quality, USP 30 <661>-compliant, non-cytotoxic, non-mutagenic, resins with incoming quality control and ID confirmation on every lot to ensure consistent materials are delivered to you
- Support materials available upon request include forced extraction studies\*\*, validation binders\*\*, certificates and other documentation upon request
- Customer support includes our highly experienced commercial specialist teams, regulatory team, quality team and regional technical support

### Thermo Scientific™ Nalgene™ Certified Platinum Clean HDPE Bottles and Carboys

Cat. No.	Description	Volume	Width, mm (in)	Height with Closure, mm (in)	Closure		No. per Pack/Case
					Size	Material	
CE-E2099-0001	Narrow Mouth Bottle	30mL (1 oz)	34.3 (1.35)	61 (2.40)	20-415	PP	12/72
CE-N2099-0008	Narrow Mouth Bottle	250mL (8 oz)	61 (2.40)	133 (5.22)	24-415	PP	12/72
CE-N2099-0016	Narrow Mouth Bottle	500mL (16 oz)	72.6 (2.86)	170.4 (6.71)	28-415	PP	12/48
CE-N2099-0032	Narrow Mouth Bottle	1L (32 oz)	91.4 (3.60)	215.9 (8.50)	38-430	PP	6/24
CE-N2199-0008	Wide Mouth Bottle	250mL (8 oz)	61 (2.40)	99.3 (3.91)	43-415	PP	12/72
CE-N2199-0016	Wide Mouth Bottle	500mL (16 oz)	72.6 (2.86)	168.2 (6.62)	53-415	PP	12/48
CE-N2199-0032	Wide Mouth Bottle	1L (32 oz)	91.44 (3.60)	199.2 (7.84)	63-415	PP	6/24
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

#### Disclaimer:

\*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](mailto:technicalsupport@thermofisher.com) if you need additional information about our products.

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

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Find out more at [thermofisher.com/platinumclean](http://thermofisher.com/platinumclean)

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