
From: Thermo Fisher Scientific [kacey.wiley.pouliot@thermofisher.com]
Sent: Wednesday, October 29, 2014 9:14 AM
To:
Subject: * Change to Irradiation Dose Range for Thermo Scientific Nalgene PET and PETG Media Bottles

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Change to Irradiation Dose Range for Thermo Scientific Nalgene PET and PETG Media Bottles

October 29, 2014

Dear Customer,

In our continued effort to improve the production workflow of our Thermo Scientific products, we will be expanding the gamma irradiation dose range from 19-28kGy to 20-45kGy for our Thermo Scientific™ Nalgene™ PET and PETG Media Bottles manufactured at our Rochester, N.Y. facility. Since the 19-28kGy irradiation dose is offered only one day per week at the irradiator, expanding the dose range to 20-45kGy will give a broader choice of irradiation scheduling options, resulting in less backorder or lead time interruptions for the impacted products to meet the growing demand of our customers.

This change is also being implemented to the PET bottles supplied to our European customers from our Newport, Wales (UK) production facility **beginning November 2014**. See copy of notification regarding manufacturing site addition [here](#).

Prior to implementation, verification will take place on representative product samples to ensure that the product performance and functionality comply with all existing specifications. Some samples are now available of select products and other samples will become available throughout the validation. Not all part numbers will be available for sampling, but all volumes and container-closure configurations will be covered.

Validation of new dose range will be completed by the end of 2014 and a validation summary can be provided at that time. Updates to Forced Extraction Study (PN 105-0001) will be available in February 2015. An updated Validation Binder for both PET and PETG will be available approximately 3 months following validation and implementation. Validation binders can be requested through ROCSupport@thermofisher.com. The actual implementation will not begin until **April 2015** to allow time for our customers to validate this change. At that time, first impacted lot numbers can be provided.

No change will take place to the resin for the container/closure, the manufacturing process, inspection procedures or any of the dimensions. As there is no change to the resin, all temperature range compatibility, chemical compatibility and reported regulatory specifications will remain the same.

A complete list of finished products affected by this change is listed below for your reference.

If you have any questions or require samples, please contact our technical support team by phone at (800) 625-4327 or +1 585 586-8800, or you may email your request to technicalsupport@thermofisher.com.

Thank you for your continued support for Thermo Scientific Nalgene products.

Sincerely,

Kacey Pouliot
Senior Product Manager
Intermediate Storage and Critical Environment, Vaccines and Biologics
Labware and Specialty Plastics
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PETG

30ml	Component Number	Object description
	2019-0030	PETG, Square Media Bottle, w/ white HDPE caps and shrink bands, 30 mL, Sterile
	342020-0030	PETG, Square Media Bottle with natural HDPE closure, 30 mL, Sterile
	342024-0030	PETG, Square Media Bottle without closure, 30 mL, Sterile
	382019-0030	PETG, Low Particulate, Square Media Bottle, w/ natural HDPE caps, 30 mL, Sterile
	302019-0030	Special Part
	642010-0660	Special Part
	642012-0360	Special Part
	642013-0740	Special Part
	642014-0010	Special Part
	669500-0726	Special Part
60ml	Component Number	Object description
	2019-0060	PETG, Square Media Bottle, w/ white HDPE caps and shrink bands, 60 mL, Sterile
	342020-0060	PETG, Square Media Bottle with natural HDPE closure, 60 mL, Sterile
	342023-0060	PETG, Square Media Bottle with septum HDPE closure, 60 mL, Sterile
	342024-0060	PETG, Square Media Bottle without closure, 60 mL, Sterile
	382019-0060	PETG, Low Particulate, Square Media Bottle, w/ natural HDPE caps, 60 mL, Sterile
	302019-0060	Special Part
	642007-0410	Special Part
	642008-0260	Special Part
	642010-0210	Special Part
	642012-0361	Special Part
	649900-0100	Special Part
125ml	Catalog No.	Description
	2019-0125	PETG, Square Media Bottle w/ white HDPE caps and shrink bands, 125 mL, Sterile
	342020-0125	PETG, Square Media Bottle with natural HDPE closure, 125 mL, Sterile
	342023-0125	PETG, Square Media Bottle with septum HDPE closure, 125 mL, Sterile
	342024-0125	PETG, Square Media Bottle without closure, 125 mL, Sterile
	382019-0125	PETG, Low Particulate, Square Media Bottle, w/ natural HDPE caps, 125 mL, Sterile
	302019-0125	Special Part
	642002-1460	Special Part
	642006-0550	Special Part
	642008-0010	Special Part
	642008-0440	Special Part
	642010-0450	Special Part
	642011-0560	Special Part
	642013-0510	Special Part
	648900-5900	Special Part
	649900-0101	Special Part
	662002-0230	Special Part
	649300-0142	Special Part
250ml	Catalog No.	Description
	2019-0250	PETG, Square Media Bottle, w/ white HDPE caps and shrink bands, 250 mL, Sterile
	342020-0250	PETG, Square Media Bottle with natural HDPE closure, 250 mL, Sterile
	342024-0250	PETG, Square Media Bottle without closure, 250 mL, Sterile
	382019-0250	PETG, Low Particulate, Square Media Bottle, w/ white HDPE caps, 250 mL, Sterile
	642005-0075	Special Part
	642007-0440	Special Part
	642010-0451	Special Part
	642010-0662	Special Part
	642013-0500	Special Part
	648900-5901	Special Part
	649900-0102	Special Part
	302019-0250	Special Part
500ml	Catalog No.	Description
	2019-0500	PETG, Square Media Bottle, w/ white HDPE caps and shrink bands, 500 mL, Sterile
	342020-0500	PETG, Square Media Bottle with natural HDPE closure, 500 mL, Sterile
	342023-0500	PETG, Square Media Bottle with septum HDPE closure, 500 mL, Sterile
	342024-0500	PETG, Square Media Bottle without closure, 500 mL, Sterile
	382019-0500	PETG, Low Particulate, Square Media Bottle, w/ white HDPE caps, 500 mL, Sterile
	642006-0555	Special Part
	642008-0445	Special Part
	642013-0490	Special Part
	648900-5902	Special Part
	649900-0103	Special Part
	302019-0500	Special Part
	342020-9500	PETG, Square Media Bottle with natural HDPE closure, 500 mL expanded, Sterile
	342023-9500	PETG, Square Media Bottle with septum HDPE closure, 500 mL expanded, Sterile
	642002-1461	Special Part
	642008-0012	Special Part
1000ml	Catalog No.	Description
	2019-1000	PETG, Square Media Bottle, w/ white HDPE caps and shrink bands, 1000 mL, Sterile
	342020-1000	PETG, Square Media Bottle with natural HDPE closure, 1000 mL, Sterile
	342023-1000	PETG, Square Media Bottle with septum HDPE closure, 1000 mL, Sterile
	342024-1000	PETG, Square Media Bottle without closure, 1000 mL, Sterile
	382019-1000	PETG, Low Particulate, Square Media Bottle, w/ white HDPE caps, 1000 mL, Sterile
	642002-1462	Special Part
	642008-0014	Special Part
	642012-0362	Special Part
	648900-5903	Special Part
	649900-0104	Special Part
	662006-0690	Special Part
	302019-1000	Special Part
	642007-0620	Special Part

2000ml	Catalog No.	Description
	2019-2000	PETG, Square Media Bottle, w/ white HDPE caps and shrink bands, 2000 mL, Sterile
	342020-2000	PETG, Square Media Bottle with natural HDPE closure, 1000 mL, Sterile
	382019-2000	PETG, Low Particulate, Square Media Bottle, w/ white HDPE caps, 2000 mL, Sterile
	302019-2000	Special Part
	642005-0750	Special Part
	649800-2500	Special Part
	642011-0640	Special Part
	642007-0670	Special Part

PET

125ml	Catalog No.	Description
	342040-0125	PET, Square Media Bottle with natural HDPE closure, 125 mL, Sterile
	342044-0125	PET, Square Media Bottle without closure, 125 mL, Sterile
	642004-0600	Special Part
	642007-0430	Special Part
	642007-0460	Special Part
	642012-0230	Special Part
	642012-0380	Special Part

250ml	Catalog No.	Description
	342040-0250	PET, Square Media Bottle with natural HDPE closure, 250 mL, Sterile
	342044-0250	PET, Square Media Bottle without closure, 250 mL, Sterile
	642012-0520	Special Part

650ml	Catalog No.	Description
	342040-0650	PET, Square Media Bottle with natural HDPE closure, 650 mL, Sterile
	342044-0650	PET, Square Media Bottle without closure, 650 mL, Sterile
	642001-0532	Special Part
	642004-0604	Special Part
	642007-0432	Special Part
	642007-0464	Special Part
	662005-0540	Special Part
	662006-0650	Special Part
	662008-0160	Special Part

1000ml	Catalog No.	Description
	342040-1000	PET, Square Media Bottle with natural HDPE closure, 1000 mL, Sterile
	342044-1000	PET, Square Media Bottle without closure, 1000 mL, Sterile
	642001-0534	Special Part
	642004-0606	Special Part
	642007-0434	Special Part
	642007-0466	Special Part

Natural HDPE Closure Only

38-430 Closure	Component Number	Object description
	342151-0240	HDPE 24-415 closure, bulk pack, sterile
	342151-0200	HDPE 20-415 closure, bulk pack, sterile
	342151-0384	HDPE 38-430 closure, bulk pack, sterile
	342141-0384	HDPE 38-430 Tamper Evident Closure, bulk pack, sterile
	642001-0601	Special Part
	642007-0730	Special Part
	642012-0030	Special Part
	642012-0300	Special Part
	649600-0560	Special Part

Septum Closure Only

38-430 Closure	Component Number	Object description
	342178-0240	HDPE 24-415 septum closure, bulk pack, sterile
	342178-0384	HDPE 38-430 septum closure, bulk pack, sterile

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