

2018.05.08

Product: Cell Culture Grade DMSO Solutions

This notification is to inform end-users that the cell culture grade DMSO products manufactured by OriGen Biomedical should not be used for human clinical applications. Instructions are provided below for return of any unused product purchased for these applications.

Dear Customer:

In December 2017, OriGen informed customers in Europe that the CE certification for the CryoPur product line had been suspended by the Notified Body. The suspension was issued as the Notified Body had not reviewed the technical file for continued conformity for an extended period of time to ensure the continued safety of the device.

In January 2018, OriGen made available an alternative cell culture grade product for customers to evaluate and determine whether the alternative would be appropriate for their application. In a follow up assessment of the technical file by our Notified Body, they identified a deficiency in OriGen's testing data, which prevented them from making a full evaluation of the stability and therefore safety of the syringe device. As a result, OriGen and our distributors will no longer be distributing cell culture grade cryopreservation solutions for customers who purchase the product for human use. OriGen is working with a consultant to remediate the testing deficiency and the CryoPur products will be made available as soon as the CE mark is reinstated under a new Notified Body.

OriGen is not aware of any adverse event associated with the use of CryoPur or the cell culture grade DMSO products. We have not identified any new risks to arise from use of the cell culture grade products relative to other DMSO products. The DMSO raw material used by OriGen was selected for its conformance to US Pharmacopeia and European Pharmacopeia monographs. The DMSO raw material is also sold by the manufacturer for healthcare and drug applications in the United States.

Customers are required to respond to this notification stating their use of the product. Customers will select either clinical applications (human diagnostic or therapeutic use) or non-clinical (no human diagnostic or therapeutic use). Customers who are using the product for non-clinical applications may retain and continue to use their product and sign this response certifying that the product is used only for non-clinical applications.

Please contact OriGen Customer Service or your distributor to request a product credit and return shipment authorization for any unused product. Customer Service will also provide instructions for the return of unused product. You may request your replacement through an email to info@origenbio.com or by faxing +1 512-617-1503. See page 3 for the required document to return with your unused material.

FIELD SAFETY NOTICE

Part Number, Description	Lot Number	Manufacture Date	Expiration Date
D-S10, 10ml syringe of 100% DMSO w/ stopcock and 15cm of SCD tubing	T20076	2018/02	2020/03
	T20101	2018/03	2020/08
	T20061	2018/02	2020/03
	T20127	2018/03	2020/08
D-S20, 20ml syringe of 100% DMSO w/ stopcock and 15cm of SCD tubing	T20062	2018/02	2020/06
	T20095	2018/02	2020/06
	T20126	2018/03	2020/06
	T20155	2018/04	2020/06
D-S30, 30ml syringe of 100% DMSO w/ stopcock and 15cm of SCD tubing	T20060	2018/02	2020/06
	T20090	2018/02	2020/06
	T20124	2018/03	2020/06
D-S50, 50ml syringe of 100% DMSO w/ stopcock and 15cm of SCD tubing	T20065	2018/02	2020/09
	T20096	2018/02	2020/09
	T20123	2018/03	2020/09
	T20143	2018/03	2020/09
D-V10, 100%DMSO, 10ml filled volume	T20043	2018/01	2020/11
	T20157	2018/04	2020/08
D-V100, 100%DMSO, 100ml filled volume	T20104	2018/03	2020/12
D-V50, 100% DMSO, 50ml filled volume	T20066	2018/03	2020/12
DXH-S7, 7.2 ml syringe of 55% w/v DMSO, 5% w/v Dextran-40 in a sterile water solution w/ stopcock and 15cm of SCD tubing	T20047	2018/02	2019/11
DXH-V100, 55% DMSO, 5% Dextran-40 w/v, Balance Sterile Water Sterile, Non-pyrogenic, Vial, 100ml filled volume	T20058	2018/02	2019/11
DXH-V50, 55% DMSO, 5% Dextran-40 w/v, Balance Sterile Water Sterile, Non-pyrogenic, Vial, 50ml filled volume	T20068	2018/02	2020/07
DXH-V7, 55% DMSO, 5% Dextran-40 w/v, Balance Sterile Water Sterile, Non-pyrogenic, Vial, 7.2ml filled volume	T20093	2018/03	2019/10

Usage Certification

Customers must state their usage of the product and return to OriGen or your distributor. Distributors must report this information to OriGen. A person with the appropriate quality or regulatory authority at the customer site must sign this section.

Clinical application Non-Clinical application

If you have selected “non-clinical application above,” please indicate whether you will return or retain the product.

Printed name of person certifying product use	Name of Institution
Signature of person certifying product use	Date

Product Return

Complete the section below and return to OriGen or your distributor for return shipment authorization and product credit. This section may be signed by any appropriate person at the customer organization.

Re: Notification on Cell Culture Grade DMSO
Item to be returned: [customer enter part and lot number]
Qty: [customer enter quantity requested to be replaced]
Customer P.O. Number: [customer enter PO to be credited]
RMA number: [customer enter RMA number received from OriGen or Distributor]

Printed name of person returning product	
Signature of person returning product	Date
