

## To whom it may concern

### Regarding: Residual solvents in cell culture products

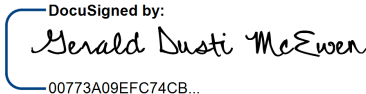
This statement is to address concerns regarding residual solvents in cell culture products as classified in International Conference on Harmonization (ICH) Guideline for Residual Solvents Q3C. Cytiva does not manufacture finished drugs but understands that cell culture products may be used in the manufacture of finished drugs and drug products.

It is hereby stated that no class 1 or class 2 residual solvents are used in Cytiva cell culture products.

According to ICH Q3C, "class 3 includes no solvent known as a human health hazard at levels normally accepted in pharmaceuticals." A list of potential class 3 solvents used in cell culture products is shown below. Not all solvents are used in all products.

Solvent	Other Names	Structure	Class
Acetic Acid	Ethanoic acid	CH <sub>3</sub> COOH	Class 3
Ethanol	Ethyl alcohol	C <sub>2</sub> H <sub>6</sub> O	Class 3
2-Propanol	Propan-2-ol Isopropyl alcohol	(CH <sub>3</sub> ) <sub>2</sub> CHOH	Class 3
Dimethyl Sulfoxide	DMSO	C <sub>2</sub> H <sub>6</sub> OS	Class 3

When class 3 solvents are included in cell culture product formulations, their levels are either well below the Permitted Daily Exposure (PDE) limits described in ICH Q3C or their concentrations are noted on the product label. Equipment is thoroughly cleaned between lots of manufactured product.

Signature:  00773A09EFC74CB...	Date:  19 December 2023
Name:  Gerald Dusti McEwen	Title  Regulatory Support Manager

The information herein is provided to the best of our knowledge and belief, based on the information we have been given and the information available to us at the time that this document was issued. The information may change as additional facts come to light, or as the circumstances warrant. Your use hereof is hence at your own risk and does not relieve you of your own responsibility for checking the suitability of our products for your intended use.



**Cytiva**  
925 West 1800 South  
Logan, Utah 84321  
USA

Cytiva and the Drop logo and all trademarks denoted with ™ are the exclusive property of Life Sciences IP Holdings Corp. or an affiliate doing business as Cytiva.

© 2023 Cytiva