

Statement

Regarding: Nitrosamines in Sepax™ C-Pro and Sefia Select™ system single-use kits and accessories

According to the World Health Organization (WHO), nitrosamines are any compound containing a nitroso (NO) functional group. These compounds are of concern because they are potential carcinogens. Nitrosamine is formed when secondary or tertiary amines react with a nitrosating agent. The most common source of nitrosating agents is sodium nitrite.

The European Medicines Agency (EMA) finalized a review under Article 5(3) of Regulation (EC) No 726/2004 in June 2020 to provide guidance to marketing authorization holders on how to avoid presence of nitrosamine impurities in human medicines. Assessment report EMA/369136/2020 "Nitrosamine impurities in human medicinal products" as adopted by the CHMP was published on 25 June 2020.

The United States Food and Drug Administration (FDA) Guidance for Industry "Control of Nitrosamine Impurities in Human Drugs" published in February 2021 (revised in September 2024) and recommends steps manufacturers of APIs and drug products should take in order to detect and prevent unacceptable levels of nitrosamine impurities in pharmaceutical products.

Product/Part name	Product code
CT-49.1 - Sepax cell separation kit - Box of 6 Units	29264738
CT-60.1 - Sepax cell separation kit - Box of 6 Units	29264739
CT-90.1 - Sepax cell separation kit - Box of 6 Units	29264740
CT-200.1 - Sefia cell processing kit - Box of 8 Units	29656477
CT-300.1 - Sefia cell processing kit - Box of 8 Units	29284866
CT-350.1 - Sefia cell processing kit - Box of 8 Units	29660965
CT.400.1 - Sefia cell processing kit - Box of 8 Units	29660968
CT-800.1 - Sefia cell separation kit - Box of 8 Units	20001
PB-100.1 - Cell Processing bag - Box of 10 Units	29660974
CPAK-100 - Box of 60 Units	29275109
CPAK-101 - Box of 60 Units	29275108

It is hereby stated that nitrosamines are neither primary raw materials of wetted components nor intentionally introduced during the manufacturing process of the listed products.

Cytiva ensures that all sourced raw materials meet specified requirements and are procured exclusively from qualified suppliers. However, complete information may not always be available from every component supplier to fully address potential contamination risks. While nitrosamines are not intentionally used by Cytiva or incorporated into supplier-sourced raw materials, the possibility of trace by-products arising from certain manufacturing processes cannot be entirely excluded.

Comprehensive extractables studies are provided in the Validation Guides, which can be accessed through the Customer Regulatory Support website: www.cytiva.com/rsf.

Signature: <small>DocuSigned by:</small> <i>Thierry Joyeux</i> <small>0419815D3928408...</small>	Date: 3 March 2026
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