

# Nitrosamine Compliance Statement

## Regarding: Cell & Gene Therapy Density Gradient Media Products

### Background

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, such as nitrous acid. 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 (MAH) on how to avoid presence of nitrosamine impurities in human medicines. Assessment report EMA/369136/2020 "Nitrosamine impurities in human medicinal products" was published on 25 June 2020 and adopted by the Committee for Medicinal Products for Human Use (CHMP).

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

Cytiva does not manufacture Active Pharmaceutical Ingredients (APIs) or drug products but understands that density gradient media products may be used in the manufacture of finished pharmaceutical products.

### Statement

It is hereby stated that sodium nitrite is not used in the manufacturing process of the products mentioned below. To the best of our knowledge, nitrosamine is not a component in the raw materials we purchase from our suppliers.

Specific analytical testing for nitrosamine is not performed.

Product/Part name	Product code
Ficoll™ Paque PLUS	17144002, 17144003
Ficoll™ Paque PREMIUM	17544202, 17544203
Ficoll™ Paque PREMIUM 1.084	17544602
Ficoll™ Paque PREMIUM 1.073	17544652
Ficoll™ PM70	17031005, 17031010, 17031015
Ficoll™ PM400	17030005, 17030008, 17030010, 17030050
Percoll™	17089101, 17089102, 17089109, 17089112
Percoll™ PLUS	17544501, 17544502
Redigrad™	17127001

Signature: 	Date: 16 October 2025
Name: Kinga Janicka	Title: Regulatory Support Manager

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## Statement

### Regarding: Animal origin in Ficoll-Paque™ PLUS and Ficoll-Paque™ PREMIUM density gradient media

It is hereby stated that the products listed below are not derived from material of animal or human origin. No animal derived material is used in raw materials or in the manufacturing process of the products. To the best of our knowledge, the BSE/TSE issue does not concern these products.

Product/Part name	Product code
Ficoll-Paque PLUS	17144002, 17144003
Ficoll-Paque PREMIUM	17544202, 17544203
Ficoll-Paque PREMIUM 1.084	17544602
Ficoll-Paque PREMIUM 1.073	17544652

Signature: 	Date: 7 January 2026
Name: Kinga Janicka	Title: Regulatory Support Manager

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