Oral Presentation

Determination of N-Nitrosodiethanolamine (NDELA) in Cosmetic Product

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ABSTRACT

N-nitrosodiethanolamine (NDELA) is a probable human carcinogen and the most frequently detected N-nitrosamine in cosmetic products (CPs). Its unintended formation arises from the reaction of amine-containing ingredients with nitrosating agents. To protect consumer health, regulatory authorities have established a strict limit of 50 µg/kg for NDELA in CPs. However, reliable analytical methods capable of selectively quantifying NDELA in complex cosmetic matrices remain limited. This study presents a novel two-step sample preparation strategy dichloromethane solvent extraction followed by solid-phase extraction using Strata X-C cartridges coupled with liquid chromatography high-resolution mass spectrometry (LC-HRMS). The method was fully validated, demonstrating excellent specificity, linearity, accuracy, and precision at concentrations relevant to regulatory thresholds. Application to 53 commercially available CPs containing known precursors or nitrosating agents revealed NDELA contamination in 28.3 % of samples. Notably, 15.1 % of products primarily shampoos exceeded the regulatory limit, with concentrations ranging from 50.5 to 159.5 µg/kg. By overcoming matrix interferences and achieving high sensitivity, this robust and selective approach provides a reliable tool for routine monitoring of NDELA in CPs. Its adoption will strengthen regulatory compliance, enhance product safety, and reduce risks associated with NDELA exposure in consumer products.

Keywords: Nitrosamine impurities, LC-HRMS, regulatory compliance, NDELA, human carcinogen, nitrosating agents

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