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Risk assessment of N-nitrosodiethylamine (NDEA) and N-nitrosodiethanolamine (NDELA) in cosmetics

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N-nitrosamine (N-nitrosodiethanolamine (NDELA), N-nitrosodiethylamine (NDEA)) and amine (triethanolamine (TEA), diethanolamine (DEA)) levels in cosmetics were determined using validated liquid chromatography-tandem mass spectrometry (LC-MS/MS) procedures. The impact of N-nitrosamine formation on the levels of TEA, DEA, nitrite and other nitrosating agents was also studied. N-nitrosamine concentrations correlated with the number of nitrosating agents and nitrite concentrations. Risk assessments, including the margin of exposure (MOE) and lifetime cancer risk (LCR) for N-nitrosamines and the margin of safety (MOS) for amines, were calculated using product type, use pattern and concentrations. Exposure to maximum amounts of NDELA and NDEA resulted in MOE>10,000 (based on the benchmark dose lower confidence limit 10%) and LCR<1×10^{-5}, respectively. Additionally, TEA and DEA in the cosmetic samples resulted in MOS values>100. Therefore, no safety concerns were associated with cosmetic products containing NDELA, NDEA, TEA and DEA in this study. However, since amines and nitrosating agents produce carcinogenic nitrosamines, their use in cosmetics should be minimized to levels as low as technically feasible.

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