Abstract:
A variety of personal care products are available on the market; however, the vast majority of these products are formulated from a limited number of constituents. Although Food and Drug Administration (FDA) regulations do not require specific tests to demonstrate the safety of a product or its individual constituents, manufacturers have the responsibility to ensure the safety of their products. The FDA states that this can be done through reliance on available safety information on individual ingredients or products with similar formulations or by performing additional toxicological tests where appropriate. The goal of this study is to demonstrate a screening-level safety assessment methodology to evaluate the safety of a constituent by determining the constituent’s frequency of use in on-market products and published safe levels of use. We identified 30 constituents in three on-market personal care products. We subsequently analyzed the National Library of Medicine’s Household Products Database and the Environmental Working Group’s (EWG) Skin Deep Cosmetic Database, two of the largest publicly available databases, for other on-market personal care products that contain these constituents and stratified the results into pre-determined product categories. Safe level of use information for each constituent was obtained by reviewing peer reviewed literature, the FDA’s generally recognized as safe (GRAS) database, and product safety publications. The results of this study showed that more than 20,000 personal care products contained one or more of the identified constituents, suggesting that these constituents are widely used in personal care products. Regarding safe levels, 22 of the 30 identified constituents were recognized as safe by the FDA or had published safe levels of use. Of the eight constituents that did not have published safe level information, there were three botanicals, two thickeners, one emulsifier, one conditioner, and one chelator. Taken together, our findings suggest that the constituents of interest are commonly used and generally safe by comparison with other on-market products and available safe level use information. However, additional evaluation through exposure assessment and risk assessments may provide additional safety information on a constituent’s specific level of use where appropriate.