Abstract:
The Food and Drug Administration (FDA) does not require testing of personal care products or their individual constituents before the products enter the market. Various trade associations such as the Scientific Committee on Consumer Safety and the Personal Care Product Council recommend tier-based assessments to evaluate the safety of personal care products and their individual constituents. The goal of this study is to evaluate the dermal irritation and sensitization potential of several commercially available hair care products using the methodology recommended by personal care product and consumer product trade associations. The first tier of testing utilized the OECD Toolbox to execute an in silico evaluation of the 30 identified ingredients in the hair care products. The potential dermal irritation and sensitization potential of each of the identified constituents was evaluated using this tool. Subsequently, two OECD in vitro guideline tests were executed to evaluate the dermal irritation and sensitization potential of the commercially available hair care products. The OECD 439, EpiDerm Skin Irritation Test (SIT), utilizes a reconstructed human epidermis to evaluate the irritation potential of a test article. The OECD 442C, Direct Peptide Reactivity Assay (DPRA), utilizes high-performance liquid chromatography (HPLC) to evaluate test article-peptide reactivity to evaluate the sensitization potential of a test article. The results from tier one in silico testing showed that 6 of the 30 ingredients had structural alerts for dermal irritation or sensitization including: behentrimonium methosulfate, dicetylpyldonium chloride, methylchloroisothiazolinone, methylisothiazolinone, panthenol, and stearamidopropyl dimethylamine. However, tier two in vitro tests showed that all of the commercially available hair care products tested were non-irritants and non-sensitizers. The results of this study demonstrate that although several constituents had structural alerts from in silico testing, subsequent in vitro testing showed that the products of interest were non-irritants and non-sensitizers. Therefore, the presence of potential irritants or sensitizers alone does not determine the safety of personal care products.