A Tiered Approach for Assessing the Safety of Polymeric Ingredients in Cosmetics and Personal Care Products

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Abstract:
Polymers are commonly used in cosmetic and personal care products as film-formers, emulsifiers, thickeners, conditioners and more, given they can be high performing and cost-effective substances. From a human health safety perspective, polymers can sometimes be classified as PLC (polymers of low concern) due to their unique physicochemical attributes, such as the potential to be minimally absorbed by the skin. However, conducting safety assessments on polymers can pose unique challenges due to their large size, the monomers from which they are synthesized, impurities in the ingredient and the potential for residuals in the final product. Consequently, there is a need for a holistic, evidence-based method that addresses these various aspects of a safety assessment for polymeric ingredients.

The objective of this work is to propose a tiered-approach that can been used for the safety assessment of polymers used in cosmetics and personal care products. Through practical application by toxicologists expert in cosmetic safety assessment, read-across, QSAR and risk assessment, the approach was developed to be fit-for-purpose for cosmetic and personal care product scenarios. The result of this work is a method which begins with understanding the physical chemical properties of the polymer (e.g., average molecular weight and molecular weight distribution, water solubility, logP, presence of residual monomers) and progresses from a more simplistic (confirming PLC) to increasingly complex (calculating multiple margins of safety for individual constituents within a polymer) evaluation. To demonstrate the proposed process and the complexity of such an assessment, a case study was implemented for a polymeric ingredient (MW > 10,000 Daltons) which contained low levels of residual monomers and impurities, several of which are not well studied, that also needed to be evaluated. The case study highlights when tools, such as the threshold of toxicological concern, read-across and QSAR modeling are (and are not) appropriate to use in the evaluation. Through this work, a framework for the questions, considerations and data requirements needed for an evidence-based safety assessment for polymeric ingredients in cosmetics and personal care products has been developed.