



TOX TOPIC*

*Documents like this created after 2014 are dubbed Express Statements.

Alternative Approaches to the Safety Assessment of Natural Ingredients and Extracts in Cosmetics

Reviewed by the SOT Regulatory and Safety Evaluation Specialty Section leadership in April 2015

Introduction

There is a growing consumer demand for personal care products and cosmetics containing natural ingredients. A major driver for this demand is the consumer's perception that such products are safer than those with synthetic ingredients and therefore healthier and eco-friendly. The personal care/cosmetics industry manufactures consume-based products that are used for personal hygiene and beautification purposes.

Issues

The increased use of personal care products and cosmetics containing botanical ingredients is becoming problematic. They are not necessarily "safer" and their potential to cause adverse side-effects in consumers must be addressed by manufacturers. While quality standards exist for certification of organic and natural cosmetics, there are no globally accepted safety assessment standards for these products. The principles used in safety evaluation of foods can be extrapolated to cosmetic ingredients where the primary route of application is dermal versus the oral route. Although relatively rare, adverse reactions to cosmetic and personal care products containing both traditional synthetic chemicals as well as natural botanical ingredients have been documented in the literature.

The safety assessment of plant materials is complex, given that traditional, standard safety testing methods for synthetic chemicals cannot be applied to natural plant ingredients as they typically contain numerous components and vary widely in composition. Therefore, chemical grouping, comparative, and read-across approaches as well as the concept of the Threshold of Toxicological Concern (TTC) are pragmatic and reliable animal alternative methodologies that can be used for the safety assessment of plant-derived cosmetic ingredients.

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of Natural Ingredients and Extracts in Cosmetics*

Additional Sources of Information:

- European Food Safety Authority (EFSA) Scientific Committee. Guidance on Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements. *EFSA Journal* 2009; 7(9):1249. [25 pp.]. Available online: <http://www.efsa.europa.eu/en/efsajournal/pub/1249.htm>
- Application of the threshold of toxicological concern (TTC) to the safety evaluation of cosmetic ingredients; Kroes et al, *Food Chem Toxicol.* 2007 Dec; 45(12): 2533-62.

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