

Safety evaluation of botanical ingredients used in cosmetics products: regulatory proposal

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Introduction: Botanicals extracts, a complex aggregate of chemicals, are used as ingredients in cosmetic products, which could be distributed in many parts of the plant, in different concentrations, therefore, does not present, *in natura*, a standardized composition. It is known that the source of the ingredient does not determine its safety. Many plants, organically grown or not, contain substances that can cause adverse reactions. Therefore, as new botanical cosmetic ingredients may contain unknown substances with toxicological properties, broad approaches to assess its safety are required. Currently, the toxicological data required by agencies such as ANVISA, FDA and EU appear to be suitable for assessing the safety of chemically well defined ingredients, but less suitable for assessing the safety of plant-derived ingredients. While regulators have issued specific guidance for the safety assessment of botanicals ingredients for use as food, similar approaches have not been considered for the safety assessment of botanical cosmetic ingredients. Thus, only after evaluation of the many natural variables set, the extraction, purification and identification, the safety of these ingredients can be conclusive. From the above it is quite clear that the establishment of specifications for quality control of botanical ingredients has been constituted as a strategic design fairly comprehensive and should include strict control of raw material. **Objective:** This paper aims to propose regulations for the safe use of botanicals ingredients in cosmetic products. **Methods:** A detailed search on bibliographic database, scientific publications and regulatory bodies, looking for the most important information from botanicals and their botanical extracts, which could be used for cosmetic purposes. Through this literature review, a regulatory proposal was outlined. **Results:** Regulatory proposal: The following points must be carefully defined and controlled: 1 Culture condition, climate, soil quality, growth conditions, use of good agricultural practices and other external factors. 2 Harvest and storage conditions; location and time of harvest; drying conditions. 3 Quality control of the sample: representativeness of the whole material; appropriate specifications for identity and purity; 4 Botanical characterization and analysis of the raw material harvested: identification of the botanical material; possibility of errors in botanical identification; fraudulent misrepresentation; morphological analyzes; chemical characterization; names. 5 Preparative steps for obtaining the extract: the state of the plant used; degree of the starting material processing. 6 Methods of extraction: solvent, type, concentration, pH; analyte of interest; validation; particle size of the plant tissues; Good Laboratory Practices. 7 Quality control of final product: composition patterns; standardization of analysis techniques and of the extraction protocol. Complete data on safety assessment of botanical extracts toxicity have not been regulated yet and it is imperative that these studies, when applicable, be conducted in any product intended to be used in humans: physico-chemical data, sensitization, skin irritation, toxicity, absorption and dermal penetration, carcinogenicity, mutagenicity, genotoxicity, reproductive and developmental toxicology, phototoxicity, photogenotoxicity, toxicokinetics and human data. **Conclusion:** The main objective of this paper is to bring up the urgent discussion about the safety evaluation of botanical ingredients in cosmetics products, which use has been growing fast, even though they have not been fully regulated yet.

Keywords: cosmetics, botanical, regulatory, toxicology.