Safety Assessment of Botanicals in Cosmetics

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Abstract

It’s a world trend that customers prefer to use personal care products (PCPs) containing natural and organic ingredients from botanicals. However, natural does not equate safe. In fact, various preparations and complex compositions of botanicals may have a potential to cause adverse effects such as skin irritation, sensitization and systemic toxicity. The current dilemma is that there is no official guideline to evaluate botanicals in PCPs and the chemical assessment cannot be easily adapted to the safety assessment of botanical substances. In line with the guideline issued by the Scientific Committee on Consumer Safety in EU, we use a strategy to guide the safety evaluation of botanical extracts (1). The first and foremost is a good characterization of the botanicals in context which include species, geographic origin, growing and harvesting conditions, manufacturing process, profile of metabolites, and analytical markers, chromographic fingerprint, known toxins. Other commonly checked points are UV absorption potential of constituent ingredients, presence of any of the 26 allergens submitted to EURL (European residual additives). For botanical ingredients with a safety history of use in food or as herbal medicines, the assessment should be started by taking into consideration all factors such as parts of plants used, genetic modifications, safety for human use, magnitude, type and scope of exposure and exposed population. The focus is to assure that botanicals intended to be used as cosmetic ingredients are similar to their traditional counterparts used in food and/or as herbal drugs in terms of composition, specifications, quality, and safety, and that exposures from cosmetic use remain far below exposures resulting from special use. Traditional botanicals should be regarded as potentially toxic and/or allergenic only if they are used in dosage often exceeding that required for therapeutic effect. It is recommended that the botanical extracts be used as cosmetic ingredients should be similar to its traditional usage in terms of composition, specifications, quality and safety.

Safety Studies on 500 generally used TCMs

Could be used as food supplements, MoH. China

TCM in TCM: Chinese Medicine

Is a broad range of medicine practices sharing common theoretical concepts, which have been developed in China and are based on a tradition of more than 2,000 years, including various forms of herbal medicine, acupuncture, massage, exercise and dietary therapy.

General assessment principles regarding botanical extracts from roots, fruits and herbs has been established (2). The botanical resource in TCM is of great interest for the cosmetic industry. Nevertheless, when it comes to TCM, additional points relating to safety should be taken into consideration during the cosmetic development.

3. Ingredient is from traditional food or herbal drug with safety data

Chinese medicine: Food may be sourced from cultivated or wild sources and may be from various parts such as seeds, berries, leaves, etc. The traditional use of a food should be comprehensively substantiated (composition, exposure, quality and safety data). Novel and novel food ingredients that have been submitted to a comprehensive assessment and registered as such could be included in this category.

Traditional herbal drugs from botanical sources should be registered as such according to various requirements according to the recording both their quality and safety should be available. The botanicals traditionally used as a cosmetic ingredient should be similar to its traditional usage in terms of composition, specifications, quality and safety.

In 2002 Ministry of Health published list of TCM that can be used as food and food additives. This list supportive in evaluation but may be insufficient for global regulatory acceptance.

Exposure analysis: The systemic exposure resulting from the cosmetic use of the botanicals should be considered lower than that resulting from its traditional use as a food or herbal drug.

Assess local tolerance: Skin and eye irritation exposure resulting from the cosmetic use of the botanicals should be considered lower than that resulting from its traditional use as a food or herbal drug.

As per knowledge or structure based programs such as DEREK, TopKat, Predictive Toxicology (3).

In Silico evaluation

Physico-chemical properties of the relevant constituents (stability, Puffarity, criteria e.g. microbiological, mycological, pesticides, heavy metals, residual solvents, other contaminants)

Level and nature of additives if any (preservatives)

Recovery conditions:

UV absorption potential of constituent ingredients of the TCM (absorbance of the 26 allergens submitted to labeling in EU)

For TCM, it may be useful to know the shape, size, color, scent and taste of the drug, which is the traditional practice for quality assessment.

Concluding remarks: leave it for good agricultural and collection practice for culture TCM.

Conclusion

The botanical TCM is a valuable mine for natural and organic cosmetic development. During safety assessment, it is helpful to combine the modern analytical tools with historical experiences. By using the indicated practices proposed above, the toxicologist in L’Oreal did many TCM safety evaluations successfully.

Reference


Simplified Facts of TCM

Characterize Ingredient- General

- Scientific name (plant family, genus, species, common names)

Several plant species may share a same TCM name, but with different application rates and toxicology profiles.

- Part(s) of the plant used

- Geographic origin (continent, country, region)

- Soil, water, weather and other natural conditions can greatly affect the composition of TCM. The differences in concentrations of constituent ingredients can be as high as 10-20 fold, even for plants harvested in different but non-prospective areas.

- Cultivar

The quality of TCM botanicals is greatly influenced by the harvested season, growing method. The optimal harvest time is when the plant reaches its right age and reach the desired turgor. The rules applied in harvest are to have more active ingredients and less toxicity (3).

Primary processes (stirring, fermentation,...)

The freshly cultivated plant of plant parts are not recognized TCM yet. They have to go through a series of primary processes including washing, trimming and drying to become raw TCM that can be stored and shipped. Further, before the raw TCM going to prescription, it has to be prepared. Preparation of TCM is a critical step to eliminate or decrease concentrations of toxic constituent ingredients and to increase concentrations of active ingredients. These preparation steps (drying, cooking, frying with expiants and etc) can qualitatively or quantitatively change the composition.

- Extraction method

- Formulation

A CHROMATOGRAPHIC “FINGERPRINT” OF SPECIFIC MARKERS CHEMICALS IS ENCOURAGED TO:

- define the variety of botanicals

- ascertain adaption and therefore confirm authenticity

A detailed chemical composition and concentration data are needed for a TTC approach.

Characterize Ingredient- Chemical

CONTENT OF MACRONUTRIENTS & MICRONUTRIENTS:

- Fats, lipids & fatty acids

- Carbohydrates (simple & complex)

- Proteins

- Vitamins

- Minerals

ANALYTICAL DATA REGARDING THE LEVEL OF NATURALLY OCCURRING POTENTIAL TOXICANTS:

- Pyrrolizidine alkaloids in comfrey

- Heavy metals

- Furanocoumarins from albizzia

- Aristolochic Acid

A representative toxicant in TCM reported in Aristolochia species and can cause damage to the plants in the root, stem, herb and fruit.

A common photosensitizing toxicant found in TCM. They are found predominantly in the orders Umbelliferae (Parsley, Carrot, Celeriac, (e.g. B Peggy, Citrus species), Moraceae and Leguminosae.

ANALYTICAL DATA ON CHEMICALS:

- Alkaloids in willow bark

- Caffeine in tea

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Specification:

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Safety Assessment

Safety Assessment may include the following (alone or in combination)

- Known components and their concentrations

- Defined use concentrations

- Defined application rates

TTC Approach:

- Substances whose physico-chemical, toxicological, and metabolic profiles are well characterized to be similar

- Extrapolation of toxicity data within a congruent group from compounds with known HOEL or NOAEL on based structural similarity and Cramer classification

In Silico evaluation:

- Must have defined chemical structure

- Must be a Structure Based Program such as DEREK, TopKat, Lead Scope

- Identification of compounds with similar structure with existing database

In vivo assays:

- Appropriate species

- Appropriate study duration

- Acceptable study quality

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