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INSIGHT INTO BOTANICAL INGREDIENTS: BENEFITS & RISKS

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White Paper

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INTRODUCTION

There is a perceived consumer preference for cosmetic and personal care products containing botanical ingredients due to their unique natural qualities and promise of transfer of wellbeing and sustenance via use of 'simple' ingredients with a perceived high efficacy.

Certain ingredients derived from botanical sources are classified based on their chemical structure and how they are isolated through suitable methods - such as extraction through solvent-based column chromatography - from plants, with an awareness of the species and genus of the plant: its bioefficacy. Although the use of ingredients derived from plants in cosmetics dates back to ancient times, the interest accelerated in recent decades with new discoveries of their potential benefits and with an increasing focus on ingredient properties which appeared exotic, nurturing or evocative to the consumer, as well as a popular perception that, in some instances, the product may have been sourced from countries via ethical and supportive economic means.

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What Are Botanicals?

A botanical Ingredient is a constituent of a personal care or cosmetic product that originates from plants such as herbs, roots, flowers, fruits, leaves or seeds. The 'botanicals' is broad, and can be applied to plant extracts, expressed juices, waxes, vegetable oils, lipids (fat-like molecules), tinctures, plant carbohydrates, essential oils, as well as purified plant components, such as antioxidants and vitamins. There are potential challenges regarding the inclusion of botanicals in cosmetic products, as these ingredients are often highly complex mixtures of chemical substances, with considerable variation in regard to their composition dependent on the part of plant the extract is from (e.g. leaf, flower, stem, peel, root or seed), species, geographical region and even the time of day it is picked.

While some botanical ingredients have been widely incorporated into food or herbal medicines with history of safety, it is a known that plant extracts can potentially create substantial, possibly adverse effects such as skin irritation, sensitisation and systemic toxicity. Consequently the term 'natural' does not always mean 'safe': some plant extracts can contain high concentrations of potentially toxic constituents and are even listed as prohibited substances in cosmetic products in the cosmetic product regulation under Annex II; e.g. Atropa belladonna (deadly nightshade) (Annex II/44), Digitalis purpurea L. (Annex II/134), aconitum – which is also known as Wolfsbane (Annex II/11).

The current dilemma is that there are no legislative guidelines to evaluate botanicals in cosmetic products, despite a brief reference given in the SCCS notes of guidance to help identify relevant information for assessment of botanical ingredients. The ASEAN Cosmetic Scientific body has also published some guidance on the safety assessment of botanical raw materials used in cosmetic products.

Processing

Depending on the targeted ingredient, various parts of the plant might be processed for use in cosmetic and personal care products. This might include the flowers, roots, seeds, leaves or other part. Some ingredients are derived directly without extraction. The plant part might be dried and/or then ground into a powder, or in some cases the plant might be squeezed or pressed to obtain the juice or oil. In all cases, the manufacturing process is carefully controlled to ensure quality and a predictable composition.

Furthermore, botanical materials produced by different purification methods - such as filtration or extraction - may differ to some extent in content. The component chemical substances in the extraction then need to be characterised before their chemical and toxicological properties can be adequately determined. Quality control issues such as contamination, reproducibility, standardization and protection of actives must be addressed.

FIGURE 1.

THE 26 ALLERGENS WHICH MUST BE DECLARED UNDER THE EU REGULATIONS ARE:

Amyl cinnamal, Benzyl alcohol, Cinnamyl alcohol, Citral, Eugenol, Hydroxycitronellal, Isoeugenol, Amylcinnamyl alcohol, Benzyl salicylate, Cinnamal, Coumarin, Geraniol, Hydroxyisohexyl 3-cyclohexene carboxaldehyde, Anise alcohol, Benzyl cinnamate, Farnesol, Butylphenyl methylpropional, Linalool, Benzyl benzoate, Citronellol, Hexyl cinnamal, Limonene, Methyl 2-octynoate, alpha-Isomethyl ionone, Evernia prunastri, Evernia furfuracea.

Characterisation

Comprehensive characterisation of botanical constituents is a foremost requirement. This can include the name of plant, name of its variety, species, genus and family, the manufacturing process, macroscopic and microscopic evaluation, organoleptic, physical and chemical specifications, a profile of micronutrients and macro, analytical markers, the chromatographic fingerprint, any known toxins, the presence of any preservatives and the microbiological specification.

Other commonly-checked points include the constitutive ingredients' UV absorption potential, the presence of any of the 26 allergens submitted to labelling in EU (see Figure 1) as well as residual solvents and additives. Where information is available detailing long-term use in herbal medicines - or their use in food - a proposed approach can be applied to compare the likely systemic exposure of the botanical ingredient when applied dermally compared to that which is considered as safe for use when used as food or a herbal supplement. The assessment should be made by considering all factors which includes: the parts of plants used, any genetic modifications, safety files for registration, the magnitude of exposure and the exposed population.

However, unlike processes within the gut and liver or within the oral cavity, the receptors in the skin are sensitive to various external factors that may have the potential to produce contact irritation, phototoxicity/ photoallergy or skin sensitization. Many plant extracts contain skin sensitisers: chemicals and proteins in natural materials. Chemical allergy in skin is a phenomenon which develops over time while protein allergy can occur very quickly. In some cases, allergens can cause skin symptoms when ingested or inhaled, and it is also possible for skin contact with chemicals to cause symptoms of an allergic respiratory nature. Some substances may cause photoallergic reactions in combination with exposure to sunlight; such toxicological parameters are instrumental in regard to defining the safety of a plant material when applied dermally.

Accordingly there is a real need to characterise the chemical component and to understand the concentration in order to provide a measure of risk from the use of the cosmetic product.

Overall, the goal is to assure that botanicals intended to be used as cosmetic ingredients are very close to their traditional counterparts which are used in food and/or as herbal drugs, in the areas of quality, composition, specifications, quality and safety, and that exposures from cosmetic uses remain below the level of exposures resulting from traditional uses.

Safety Assessment

When assessing the safety of botanical ingredients, a fundamental issue is the phytochemical characterisation of the plant source, as well as data concerning contamination, adulteration and hazardous residues. The same comparative approach used in the safety assessment of GMplants may be applied to novel botanical personal care products (PCP) ingredients, with comparator(s) being the parent plant or varieties of the same species.

Chemical grouping allows the estimation of toxicological endpoints on the basis of data from related substances (congeneric groups) with physical/chemical properties producing similar toxicities.

The Threshold of Toxicological Concern (TTC) and Dermal Sensitisation Threshold (DST) are tools for the assessment of trace substances or minor ingredients. The TTC is a pragmatic, risk assessment-based approach that has attained regulatory acceptance for food, and as such has been recently adapted to address cosmetic ingredient safety. It is comprised of three classes; see Figure 2.

Throughout analysis, consideration should be made to Type I hypersensitivity (which is often an immediate reaction) and Type IV sensitisation (which is delayed and may include photoallergy).

In risk assessment - along with in vitro, in vivo and clinical tests - the identification of a suitable NOAEL (No Observed Adverse Effect Level), the Threshold of Toxicological Concern is deployed in conjunction with Cramer class, or in silico modelling, and can be used to support the safety analysis of potential fractions of the botanical extract of unknown composition and/or of a nondocumented safety profile.

FIGURE 2.

THE THRESHOLD OF TOXICOLOGICAL CONCERN IS COMPRISED OF THREE MAIN CLASSES, REGARDING PRODUCT SAFETY.

1. Class I contains substances of simple chemical structure with known metabolic pathways and innocuous end products which suggest a low order of oral toxicity.

2. Class II contains substances that are intermediate. They possess structures that are less innocuous than those in Class 1 but they do not contain structural features that are suggestive of toxicity like those in Class 3.

3. Class III contains substances with a chemical structures that permit no strong initial impression of safety and may even suggest a significant toxicity.

FUTURE CHALLENGES

The experience from dietary supplements or herbal medicines showed that a 'natural' route can not be assumed to be safe by default. Therefore, pragmatic approaches for safety and quality standards of botanical ingredients are crucial, with the consideration of consumer safety paramount, as adverse dermal effects of botanicals include irritation, phototoxicity, immediate-type allergy and more. Despite inherent challenges, the demand for botanicals leads to innovation in what appears to be an ever-evolving, highly-stimulating field: product innovation is actively sought by the consumer, driving a dynamic market - with many companies replacing or reformulating approximately a quarter of their products annually - in which the perceived 'active' ingredients of the botanical product are sought to directly and intimately interface with the consumer, and with scientific innovation so prelevant that it has become fundamental to many marketing campaigns. Therefore the need to create safe, effective and compliant products is paramount.

MEET OUR EXPERT

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Chris Brennan has extensive experience in Organic, Medicinal, Combinatorial and Analytical Chemistry gained within the pharmaceutical industry. He has been involved in designing the lead optimisation chemistry programmes for a number of potential drug candidates that have since moved on to preclinical stages.

He was appointed as a Postdoctoral Fellow at the CNRS in Gif-sur-Yvette and has published a number of scientific papers and patents in international journals. He is currently Manager of the Intertek Toxicology group based at Leicester and is one of Intertek's global experts in cosmetic safety assessment and regulation.

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