



ALLERGENIC SUBSTANCES concerned by the 7th amendment

Position paper

In June 2003, UNITIS published a first position paper explaining:

- The possible impact of the provisions of the 7th amendment of the European Cosmetic Directive concerning 26 allergenic substances on the use of ingredients from botanical origin,
- The launching of a significant program of works aiming to determine this impact plant by plant and to optimize the information which has to be given to the cosmetic industry regarding such ingredients.

Today, these works have been performed by an ad hoc Task Force through a deep study of existing literature, recourse to the knowledge of botanical ingredients manufacturers and specific dosages when necessary.

They were only focused on the 26 allergenic substances listed in the 7th amendment of the European Cosmetic Directive. All other questions related to allergenic phenomenon have to be dealt with separately.

As a result, according to existing relevant literature, scientific knowledge and techniques, the position of UNITIS Members is the following:

- 1 - Only 16 out of the 26 listed substances concern botanical ingredients because being possibly found in plants – *See Annex*.
The other substances are synthetic only or, in the case of Evernia, botanic species themselves.
- 2 - **229 plants**, and consequently their extracts :
 - **Either do not contain any** of these 16 allergenic substances,
 - **Or contain unquantifiable traces** of one or several of these 16 allergenic substances.

All these plants listed can be used without any impact on cosmetic products labelling.

- 3 - **25 plants** are recognized as **containing limited amounts** of one or several of said 16 allergenic substances.

In such plants, the total content of these 16 allergenic substances is between 1 ppm and 500 ppm.

Unless they are prepared through a specific process enabling to eliminate them totally, total extracts from these plants, up to a proportion of 1 part of plant for 5 parts of extract, will have a total content of the 16 allergenic substances going from 0,2 ppm to 100 ppm.

In such cases the information given to the cosmetic industry can be standardized at the level of 100 ppm or less of a total of the 16 allergenic substances.

In case of extracts with higher concentration the content in the 16 allergenic substances has to be approached case by case.

- 4 - **59 plants** are **containing significant amounts** of one or several of the concerned 16 allergenic substances.

For such plants, UNITIS recommends to practice individual dosages of the 16 allergenic substances in the extracts unless the process of extraction guarantees their elimination.

Nevertheless, due to the quality of the information available on these plants, routine dosages are not necessary. The dosage on 3 industrial batches will be representative enough.

The results of works performed by UNITIS Task Force are in hands of UNITIS Members assorted with references of relevant literature and results of tests. They simplify and optimize the way to assist cosmetic industry in complying with its legal obligations for more than 310 plants/parts of plants and their extracts.

Although these lists include plants frequently used, they cannot be considered as exhaustive and, in order to maintain its contribution in the future, UNITIS will keep its Task Force operational in order to study and classify any new plant according to here above categories and lists.

Already, a first waiting list has been constituted and will be studied during the next months.

