

Summary of the application: Aqueous ethanolic standardized extract of *Labisia pumila* (SKF7™)

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This novel food application is related to SKF7™, an aqueous ethanolic standardized extract of *Labisia pumila*. Approval is sought under Regulation (EC) No 2283/2015 of the European Parliament and of the Council of 25th November 2015 concerning novel foods. The ingredient falls under the following category: “Food consisting of, isolated from or produced from plants and their parts”. The applicant requests the authorization to use SKF7™ in food supplements at the dose of 750 mg/day. Children under 18 years, as pregnant and lactating women, are excluded from the target population.

SKF7™ consists of a standardized aqueous ethanolic extract of *L. pumila*. Briefly, after a control of raw material, the plant is washed, dried and ground. The ground plant is then extracted with a mixture of water and ethanol. The liquid extract is then concentrated and spray dried. The final extract is then stored until encapsulation.

All the specifications of the aqueous ethanolic standardized extract of *Labisia pumila* are in accordance with European standard and regulations. Analyzes have demonstrated the lack of various contaminants: heavy metals, microbiological contaminants, pesticides, PAH, PCB/dioxins, and mycotoxins. Moreover, ethanol residues are below 1%.

The safety of the extract has been highlighted by four toxicity study (GLP and OECD compliant studies): a bacterial reverse mutation test (OECD 471), one in vitro chromosome aberration test (OECD 473), one in vivo micronucleus test (OECD 474) and one sub-chronic 90-day toxicity study (OECD 408). In this last study, the NOAEL has been measured at 2000 mg/kg BW/day. Regarding allergenicity, no safety concern has been highlighted in several clinical trial assessing the effects of *L. pumila*.

Therefore, SKF7™ is well-characterized and compliant with European regulations. The product is safe and devoid of significant allergic potential. The aqueous ethanolic standardized extract of *Labisia pumila* does not present consequently any potential hazard the European population in the conditions proposed by the applicant.