

## Summary of the dossier: Ashitaba sap powder

Applicant: Japan Bio Science Laboratory (JBSL)-USA, Incorporated, 1547 Palos Verdes Mall #131, Walnut Creek, California, 94597 U.S.A.

This is an application for authorisation to place on the market ashitaba sap powder as a novel food to be used in food supplements at a maximum recommended use level of 200 mg/day (providing at least 16 mg total chalcones/day). It is not intended to be an alternative or replacement to any existing foods consumed as part of the normal diet.

The novel food ashitaba sap powder is comprised of the sap of the *Angelica keiskei* (ashitaba) plant with cyclodextrin present as an excipient. The final novel food contains not less than 8% total chalcones comprised of xanthoangelol and 4-hydroxyderricin at ca. 5% and 3%, respectively.

The production of the novel food utilises processes that have a long history of use in the food industry and appropriate controls are in place. Analytical data demonstrate that the final product is consistent and complies with the internally established specifications. Additional batch analyses demonstrate that ashitaba sap powder is not a significant source of contaminants including heavy metals, microorganisms, polycyclic aromatic hydrocarbons, inherent plant toxins, and pesticides.

The safety of ashitaba sap powder is substantiated by the history of consumption of its constituents (ashitaba plant and cyclodextrin) along with product-specific toxicological studies. Specifically, ashitaba sap powder was demonstrated not to be mutagenic nor genotoxic in a series of studies including the in vitro bacterial reverse mutation test, in vitro mammalian chromosomal aberration test, and the in vivo mouse micronucleus test. In a 90-day repeat-dose oral toxicity study in rats, a no-observed-adverse effect level (NOAEL) of 300 mg/kg body weight/day for both males and females was established for ashitaba sap powder on the basis of an increased incidence of dilated lacteal in the jejunum of rats given 1,000 mg/kg body weight/day. In consideration that the maximum recommended dose of ashitaba sap powder will be 200 mg/day in food supplements (equivalent to 2.9 mg/kg body weight/day for a 70 kg individual), this provides at least a 100-fold margin of safety relative to the reported NOAEL. Furthermore, product-specific studies in humans demonstrate that ashitaba sap powder is well-tolerated when given at up to 220 mg/day (containing approximately 17.6 mg chalcones/day) for 12 weeks.

On the basis of the information described herein, the body of available scientific data on the novel food and its components, ashitaba sap and cyclodextrin, supports the safety and suitability of the novel food for its intended use in food supplements.

The application has been compiled in line with the administrative and scientific requirements of Commission Implementing Regulation (EU) 2017/2469 laying down for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods. It is also in line with the European Food Safety Authority (EFSA) guidance on the preparation and presentation of an application for authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283.