Summary of the application: Extract derived from *Panax notoginseng* and *Astragalus membranaceus*

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The novel food application concerns request for authorisation of extract derived from *Panax notoginseng* and *Astragalus membranaceus* (brand name: AstraGin™).

AstraGin™ is a botanical extract derived from the roots of both *Panax notoginseng* and *Astragalus membranaceus* using an extraction and processing technology. The specifications of AstraGin™ are detailed and are in compliance with the European standards and regulations. Microbiological, heavy metals and pesticide analyses are especially conforming. The production of AstraGin™ is achieved under high standards of Quality Management and GMPs. The composition of AstraGin™ results in a safe and stable ingredient.

The suggested daily efficacious oral intake for adults is 50 mg/d of AstraGin™ in food supplements. The bacterial reverse mutation test (AMES test, OECD 471) was performed to evaluate the mutagenic potential of AstraGin™, by quantifying its ability to induce reverse mutations in *Salmonella typhimurium* and *Escherichia coli* strains in the presence or absence of a metabolic activation (S9 mix). According to the results, there was no sign of cytotoxicity for the bacterial strains, even at high dosage (5000 µg/plate). AstraGin™ was judged to have no reverse mutagenic potential under these test conditions. The mutagenic potential of AstraGin™ was also determined using in vitro mammalian cell gene mutation test (HPRT gene mutation, OECD 476). Cells were treated with AstraGin™ at different concentrations (0.625 to 5 mg/ml). No cytotoxicity effect was observed at 5 mg/ml without S9 mix. In the absence of S9 metabolic activation, AstraGin™ did not induce gene mutation at the HPRT locus in the cultured mammalian cells used. A subchronic 28-day oral toxicity study (OECD 407) was performed using AstraGin™. Rats were administered either 0, 100, 300 or 1000 mg/kg bw/day of AstraGin™, for 28 days. No mortality and no clinical signs or abnormalities in behavior, motor activity, or general state were observed in animals. According to the results, this study didn't show any side effects of AstraGin™ at a high dosage, and a NOAEL of 1000 mg/kg bw/day has been determined. The repeated dose 90-day oral toxicity study in rodents (OECD 408) was carried out to evaluate the toxicity of AstraGin™ in rats. AstraGin™ was administered daily at four dose levels (0 to 1000 mg/kg bw). No specific histopathological changes in the organs were observed in the groups. Based on observations, AstraGin™ may not induce pathological changes and this study supports the safety of AstraGin™ in rats at 1000 mg/kg bw. AstraGin™ is also considered to be Generally Recognized As Safe (GRAS) according to the rules and regulations administrated by the FDA. In conclusion, AstraGin™ characterization is complete, and 5 batches of AstraGin™ have been provided in order to be compliant with all the standards of the European Regulation. Moreover, the product has been shown to be safe through a bacterial reverse mutation test, an in vitro mammalian cell gene mutation test, a 28-day and 90-days subchronic toxicity studies in rats to conclude that AstraGin™ does not present any potential hazard for the European population (Appendix A & B). Absorption, distribution, metabolism and excretion of Panax notoginseng and Astragalus membranaceus have been identified and no study mentioned the allergenic potential of these plants and their extracts.