

Summary of the application: Polyphenols derived from the lychee fruit (*Litchi chinensis*) and green tea leaves (*Camellia sinensis*)

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The novel food application concerns request for authorisation of polyphenols derived from the lychee fruit (*Litchi chinensis*) and green tea leaves (*Camellia sinensis*)(brand name: Oligonol®).

The novel ingredient is Oligonol®, polyphenols derived from lychee fruit (*Litchi chinensis* Sonn.) and green tea leaves [*Camellia sinensis* (L.) Kuntze]. Oligonol® consists mainly of monomeric flavan-3-ols, as well as procyanidins formed from the condensation of these monomeric units. Oligonol® is manufactured from a 5:1 mixture of extracts from the lychee fruit and green tea leaves, which undergoes an oligomerisation process whereby the polyphenols present are cleaved into monomers and lower molecular weight oligomers. The phenolic content of Oligonol® is >80% of the total mixture.

Oligonol® is proposed for use in a variety of conventional foods and beverages at use levels ranging from 100 to 1,150 mg/kg or mg/L. The mean exposure to Oligonol from the proposed food uses was estimated to range from 1.7 to 8.8 mg/kg body weight/day in adults. Oligonol® is also intended for use in food supplements at 200 mg/day.

The safety of Oligonol under the intended conditions of use is supported by the extensive history of safe consumption of both lychee fruit and green tea leaves, which are used as the source of polyphenols for the manufacture of Oligonol®. The safety of Oligonol® is also supported by several product-specific toxicological studies. No toxicologically relevant effects were reported in two 90-day studies where Sprague-Dawley rats were orally administered Oligonol®, in which the no-observed-adverse-effect level (NOAEL) was determined to be 1,000 mg/kg body weight/day (highest dose tested in both males and females). These findings were further corroborated by the absence of toxicological effects reported in a 90-day feeding study conducted in mice, which were administered doses of Oligonol® at up to 200 mg/kg body weight/day. Oligonol® was also well-tolerated in several human studies, with no adverse events reported and no treatment-related changes in haematology or serum biochemistry parameters observed in subjects consuming 200 to 600 mg/day of Oligonol® for a period of 3 months. Data from oral toxicity studies (i.e., acute and short-term) and human studies conducted with an Oligonol®-like product, which is manufactured using the same oligomerisation process (but from different starting materials) and contains similar polyphenolic composition as Oligonol®, further corroborate the safety of Oligonol®.

Collectively, the scientific evidence demonstrates that Amino Up's Oligonol® ingredient would not produce adverse effects on human health under the proposed conditions of use in conventional foods and food supplements.