

Summary of the dossier: Blend of *Tamarindus indica* seeds and *Curcuma longa* rhizome extracts

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This is an application for authorisation of a blend of *Tamarindus indica* seeds and *Curcuma longa* rhizome extracts for use in food supplements in the European Union (EU).

The application has been prepared in accordance with the requirements of Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, 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 and EFSA's Administrative guidance on the submission of applications for authorisation of a novel food pursuant to Article 10 of Regulation (EU) 2015/2283.

The novel food provides 65% of proanthocyanidins and 3% of curcuminoids. It is intended to be used as or in food supplements in Europe, delivering not more than 400 mg of the novel food/day, providing daily dose of proanthocyanidins of at least 260 mg and a daily dose of 12 mg of curcuminoids.

The novel food is intended for use in healthy adults excluding children, pregnant, lactating women.

The information provided on the identity, composition, specifications and lack of batch-to-batch variability of the novel food demonstrates control of the production process and that the product is compliant with EU regulations and neither nutritionally disadvantageous substance nor toxic contaminants are present. Moreover, preclinical and clinical studies performed showed that the product wasn't associated with toxic effects in animals nor adverse effects in human at the proposed use levels.

An AMES assay and an in vivo mouse bone marrow micronucleus assay showed that the novel food is not associated with mutagenic nor genotoxic potential. A 90-day toxicological study in rats to which the novel food was administered established a NOAEL of 1000 mg/kg of body weight/day.

In a randomized, double-blind, placebo controlled study, conducted in healthy adults, ingestion of up to 400 mg/d of the novel food/day is safe after 90 days of supplementation (i.e., no clinically adverse effects on haematology, biochemistry parameters, nor urine analysis results or vital signs).