

Summary of the dossier: Curcuminoid-containing turmeric extract

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This is an application for curcuminoid-containing turmeric extract as a novel food ingredient in the European Union (EU). Curcuminoid-containing turmeric extract is a micro-granulated formulated ingredient composed of turmeric powder extract, gum arabic, quillaia extract and sunflower oil, intended to be used in several food categories and in food supplements.

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.

Curcuminoid-containing turmeric extract is manufactured by homogenisation, milling, pasteurisation, spray drying and sieving, in compliance with the principles of Hazard Analysis Critical Control Points (HACCP). Analysis of several independent, representative batches of curcuminoid-containing turmeric extract demonstrates that the manufacturing process produces a consistent ingredient that complies with the proposed food-grade specifications, with no contaminants detected above stringent specification or EU limits (where applicable).

Curcuminoid-containing turmeric extract is considered not to be nutritionally disadvantageous as the main components (turmeric extract, gum arabic and quillaia extract) have not been reported to interact with nutrient intakes. The results of a proprietary human bioavailability study demonstrate that curcuminoid-containing turmeric extract provides a more bioavailable source of curcuminoids than standard turmeric extract, and is as effective (even at a relatively lower dose) at providing a bioavailable source curcuminoids compared with other currently marketed turmeric extract formulations that are also intended to provide a bioavailable source of curcumin.

Proprietary toxicology studies [*in vitro* genotoxicity studies (bacterial reverse mutation test and *in vitro* mammalian cell micronucleus test) and a subchronic 90-day rat study] have been conducted to support the safety of curcuminoid-containing turmeric extract. There was no evidence of genotoxicity in the *in vitro* tests, and the highest dose tested in the 90-day study was established as the no-observed-adverse-effect-level. Curcuminoid-containing turmeric extract also contains no detectable protein residues, indicating that it has low/no allergenic potential.

Together, the weight of the available evidence on curcuminoid-containing turmeric extract supports the safe use of the ingredient under the proposed conditions of use.