

Summary of the dossier: Solid lipid curcumin particle (SLCP) preparation

Applicant: Verdure Sciences, 17150 Metro Park Court, Noblesville, IN 46060, USA

Verdure Sciences intends to introduce solid lipid curcumin particle (SLCP) preparation as a novel food ingredient in the European Union (EU). The final ingredient comprises curcuminoids (curcumin, demethoxycurcumin, and bisdemethoxycurcumin) derived from solvent extraction of turmeric (*Curcuma longa* L.) rhizomes, and processing aids. It is intended for use in food supplements for adults.

Specification parameters for the identity and compositional characteristics of the ingredient, as well as appropriate limits for microbiological and heavy metal parameters, have been established. Analytical data for several independent representative batches of SLCP preparation demonstrate that the production process results in a final ingredient that consistently meets the proposed specifications and is absent of potential contaminants such as heavy metals, microorganisms, camphor and 1,8-cineole, pesticides and mycotoxins. SLCP preparation has also been shown to be stable for its intended shelf-life.

The results of a human pharmacokinetic study conducted with SLCP preparation demonstrated that curcumin bioavailability was markedly increased following consumption of SLCP preparation compared with a standard 95% curcuminoids extract (which did not show any plasma exposure). Considering that SLCP preparation is a blend of turmeric extracted curcuminoids and processing aids, the numerous published absorption, distribution, metabolism, and excretion (ADME) studies of the individual constituents (turmeric/curcumin extract, processing aids) also combine to characterise the ADME of the ingredient as a whole.

SLCP preparation is considered not to be nutritionally disadvantageous for consumers under the proposed conditions of use.

Pivotal toxicology studies conducted with SLCP preparation include genotoxicity studies (*in vitro* and *in vivo*) and a 90-day gavage toxicity study in rats. SLCP preparation was confirmed as non-genotoxic, and the highest dose tested was the no-observed-adverse-effect level (NOAEL) in the 90-day study. This NOAEL provides a sufficient margin of safety compared with the highest exposure from its intended use in food supplements for adults. SLCP preparation was also well tolerated in several controlled clinical trials.