

Summary of the Application: Calcium Fructoborate

Applicant: VDF FutureCeuticals, Inc., 300 West 6th Street, Momence, Illinois 60954 USA

The application concerns request for authorisation of calcium fructoborate as a novel food. The novel food calcium fructoborate is the calcium salt of a bis(fructose) ester of boric acid in the form of a tetrahydrous powder. The structure of fructoborate comprises 2 fructose molecules complexed to a single boron atom.

Calcium fructoborate is synthesised from crystalline fructose, boric acid, and calcium carbonate, and the final product is a fully complexed ingredient. Calcium fructoborate is intended to be marketed as a functional ingredient for use in food supplements and will be sold in solid crystalline form at a recommended use of up to 220 mg/day in adults aged 19 years and older. Under the intended conditions of use, a daily serving of 220 mg calcium fructoborate would contribute 6 mg boron, 10 mg calcium, and 191 mg fructose/day.

The safety of the novel ingredient is substantiated by product-specific toxicological studies. Calcium fructoborate is neither mutagenic nor genotoxic based on the results of a reverse mutation assay and an in vitro mammalian micronucleus assay. On the basis of a 90-day oral toxicity study in rats, a no-observed-adverse effect level (NOAEL) of 1,200 mg/kg body weight/day (highest dose tested) was established, which is well above the intended use level of calcium fructoborate (i.e., 3 mg/kg body weight/day in consideration of a 70 kg individual consuming 220 mg calcium fructoborate/day). Calcium fructoborate was also evaluated in a number of short-term human studies that provide supportive evidence for the tolerability of the novel ingredient at levels of up to 220 mg/day in the adult population. Safety is further supported by the established history of safe use of the individual components (i.e., boron, calcium, and fructose). The relative contribution of the individual components under the intended condition of use of calcium fructoborate as an ingredient in food supplements would result in exposures well within the tolerable upper intake levels (ULs) derived from various authoritative opinions and/or background dietary exposure levels. Additionally, the safety of calcium fructoborate is corroborated by the presence of fructose-boron complexes that are naturally present in plants consumed as part of a normal diet and a 17-year history of use in the United States and Canada without a single report of an adverse health consequence.

In summary, the available data from toxicology and human studies on calcium fructoborate itself, authoritative reviews on the components of calcium fructoborate, and background dietary consumption of fructose-boron complexes support the safe use of calcium fructoborate in food supplements at the intended use of up to 220 mg/day in the adult population.