

## Public summary of the dossier

This summary of the dossier is provided in accordance with the requirements of Article 10 of Regulation (EU) 205/2283.

(a) Name and address of the applicant

Huve Nutraceuticals Ltd  
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Sofia 1113 Bulgaria

(b) Name and description of the novel food

DHA-rich oil from *Schizochytrium limacinum* A2.

DHA is synthesised in marine plants and algae by the elongation of  $\alpha$ -linoleic acid (ALA). It accumulates in fish and other marine animals that consume algae and is passed on to other species through the food chain. Though terrestrial plants can produce small to moderate amounts of ALA, humans cannot synthesise ALA. As a result, humans must directly consume DHA. DHA plays various roles throughout the body and is utilized in maintaining the function of the brain and eye. Notably, foetal development and infancy are key windows during which sufficient DHA levels are necessary for optimal mental and visual development and performance in later life.

(c) Description of the production process

The novel food is produced in compliance with GMP and HACCP using only ingredients permitted by EU regulation. The microalgae is grown and fermented under controlled conditions. Once fermentation is complete, the broth is heat treated to ensure no viable cells remain. The cooled broth undergoes hydrolysis, separation, neutralisation, washing, winterisation, filtration, bleaching, deodorisation, and stabilisation before being packed.

(d) Detailed composition of the novel food

The novel food that is the subject of this application complies with specifications for the novel food *Schizochytrium* sp. oils (Regulation (EU) No 2017/2470).

(e) Scientific evidence demonstrating that the novel food does not pose a safety risk to human health

DHA-rich oil is already authorised for use in food in the EU and has a long history of safe use. Numerous publications describing ADME, toxicity studies and human studies and supporting the safety of the novel food have previously been assessed by EFSA.

(f) A proposal for the conditions of intended use and for specific labelling requirements which do not mislead the consumer or a verifiable justification why those elements are not necessary

The novel food is intended to replace other DHA-rich algal oils used in infant formula and follow-on formula, the use levels of which are defined by regulations.



The novel food is also intended for use in food supplements at a level of 3 g/day.

The designation of the novel food on the labelling of the foodstuff containing it shall be “Oil from the microalgae *Schizochytrium* sp.”.