

Summary of the application: *Schizochytrium* sp. oil

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This novel food application is related to BioDHA, a *Schizochytrium* sp. oil rich in DHA. This oil is already authorised in a range of foodstuffs in EU. This application aims to request an extension of use of BioDHA in infant and follow-on formulae. BioDHA oil is compliant with the specifications laid down in the Regulation (E) No 2017/2470.

The application has been prepared in accordance with the administrative and scientific requirements of Commission Implementing Regulation (EU) 2017/2469 laying down for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods, and with 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.

The Novel Food consists in a DHA-rich *Schizochytrium* sp. oil, called BioDHA. Analyses performed on five independent batches showed that BioDHA is compliant with the specifications of *Schizochytrium* sp. oils already authorized in the European Union (Regulation (EU) 2017/2470). Moreover, analyses have demonstrated the lack of any contaminant (microbiological contaminant, heavy metals, solvents, PCB and dioxins, PAH, pesticides, melamine and 3-MCPD) in BioDHA. The oil does not present any variability among batches, and is stable under standard conditions of storage for such products.

It is well known that DHA is devoid of any safety concern in humans. The available toxicity studies have demonstrated a lack of genotoxicity/mutagenicity, as of acute and chronic toxicity. Due to the lack of proteins, DHA-rich oils from *Schizochytrium* sp. are not associated with any allergenicity. Reproductive and developmental toxicity studies have demonstrated the safe use of such oils for infant and young children.

To conclude, BioDHA is well-characterized and compliant with European Regulations, and notably with the specifications of *Schizochytrium* sp. DHA-rich oils presented in Regulation (EU) 2017/2470. Moreover, as for other DHA-rich oil from *Schizochytrium* sp., BioDHA is safe for a use in infant and follow-on formulae.