

Summary of the application: Cetylated fatty acids

Applicant: Pharmanutra S.p.A., Via Delle Lenze 216/b, 56122 Pisa, Italy

This is an application for cetylated fatty acids as a novel food ingredient in the European Union (EU). Cetylated fatty acids is synthesised from cetyl alcohol, myristic acid and oleic acid, and mixed with olive oil. It is intended for use in food supplements for the general population, excluding infants and young children.

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.

Cetylated fatty acids is manufactured following the principles of Hazard Analysis Critical Control Points (HACCP). Analysis of several independent, representative batches of cetylated fatty acids demonstrates that the manufacturing process produces a consistent ingredient, that complies with the proposed specifications and shows absence of contaminants such as heavy metals, microbials, 3 monochloropropanediol, glycidyl fatty acid esters, dioxins and polychlorinated biphenyls, polycyclic aromatic hydrocarbons, and erucic acid.

Cetylated fatty acids is a source of fatty acids (including the essential fatty acid linoleic acid), which are present in commonly used vegetable oils that are consumed as part of the regular European diet. It is not intended to replace fatty acids from other sources. It is therefore considered that consumption of cetylated fatty acids would not be nutritionally disadvantageous for the consumer.

As well as safety being supported by the history of safe consumption of the fatty acids in the regular diet, the safety of cetylated fatty acids was assessed in a comprehensive battery of toxicological studies, including a bacterial reverse mutation assay, an in vitro mammalian cell micronucleus test in human lymphocytes and a repeated dose 90-day oral toxicity study. These studies were all conducted with a test article that is representative of the material intended to be commercially marketed and they were performed in accordance with the Organisation for Economic Co-operation and Development (OECD) principles of Good Laboratory Practice and appropriate OECD test guidelines. Furthermore, the allergenic potential of cetylated fatty acids is negligible.

Together, the weight of the available evidence on cetylated fatty acids supports the safe use of the ingredient under the proposed conditions of use.