

Summary of the application: Clary Sage (*Salvia Sclarea*) Seed Oil

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This is an application for the approval of Clary sage (*Salvia sclarea*) seed oil as a novel food ingredient in the European Union (EU). Clary sage seed oil is obtained by cold press extrusion of the seeds of *S. sclarea* Lamiaceae and is rich in alpha-linolenic acid (ALA). The lipid content of the oil consists primarily of the fatty acids alpha-linolenic (46 to 56%), oleic (20 to 30%), and linoleic (16 to 18%). Clary sage seed oil is intended to be used as food supplements as a source of omega-3 fatty acids.

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.

Clary sage seed oil is produced by cold press extrusion of the seeds, in compliance with the principles of Hazard Analysis Critical Control Points (HACCP). Analytical tests conducted using independent, representative batches of Clary sage seed oil shows that the production process results in a consistent product that complies with the proposed final product specifications with no detectable levels of contaminants such as heavy metals, microbials, pesticides, and other inherent constituents of concerns. Analytical data on the fatty acid, sterol, and tocopherol profiles as well as the lipid composition of Clary sage seed oil demonstrate that these parameters are within the typical ranges reported in flaxseed oil, which has a long history of safe use, and buglossoides oil and chia seed oils, which are currently permitted for use as food ingredients in the EU. Stability data are available to demonstrate that Clary sage seed oil does not undergo oxidation or hydrolysis of fatty acids to any significant degree over a 24-month time span.

Extensive ADME data are available in the published literature for the individual fatty acids in the novel food, and these studies demonstrate that fatty acids have well established metabolic pathways and structural, storage and metabolic functions in the body. The safety of Clary sage seed oil under the intended conditions of use is based on the weight of scientific evidence. Specifically, the pivotal data to support the safety of Clary sage seed oil include that it is almost entirely composed of fatty acids that are commonly consumed as part of the regular diet in the EU, and that it is compositionally similar to flaxseed oil, which has a long history of safe use, as well as buglossoides oil and chia seed oil, which are approved for use in food in the EU. Data from human studies support the safety of the intakes of ALA under the proposed conditions of use of Clary sage seed oil, while the intakes of the other primary fatty acids, linoleic acid and oleic acid, are within the recommended dietary reference values set by EFSA and AFSSA. Data from Tier 1 genotoxicity and subchronic toxicity studies and a Tier 2 prenatal developmental toxicity study conducted with oils of similar composition provide corroborative evidence of the safety of Clary sage seed oil. Furthermore, the results of preclinical toxicity studies on the primary fatty acids in Clary sage seed oil (i.e., ALA, linoleic acid, and oleic acid) and other vegetable oils of similar composition provide

corroborative evidence of the safety of Clary sage seed oil. Considering that Clary sage seed oil contained no detectable levels of total protein, Clary sage seed oil is not expected to have allergenic potential.

Based on the weight of the available evidence on Clary sage seed oil and its primary fatty acid constituents, Naturesage considers that there is sufficient data to support the safe use of Clary sage seed oil as an ingredient under the proposed condition of use.