

Public summary of the dossier: Dried biomass of *Galdieria sulphuraria*

Applicant: Fermentalg, 4 rue Rivière, 33500 Libourne, France

This novel food application is related to a dried biomass of *Galdieria sulphuraria*. Approval is sought under Regulation (EC) No 2283/2015 of the European Parliament and of the Council of 25th November 2015 concerning novel foods. The ingredient falls under the following category: “Food consisting of, isolated from or produced from micro-organisms, fungi or algae”. The applicant request the authorization to use of the dried biomass of *G. sulphuraria* in food supplements and in a range of foodstuffs. Children under 18 years, as pregnant and lactating women, are excluded from the target population.

The application has been compiled in line 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. It is also in line 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. All the specifications of the dried biomass of *G. sulphuraria* are in accordance with European standard and regulations. Analyses have demonstrated the lack of various contaminants: heavy metals, microbiological contaminants, pesticides, PAH, PCB/dioxins, etc.

The safety of the dried biomass has been highlighted in accordance with the tiered approach proposed by EFSA, including three toxicity studies (GLP and OECD compliant studies): a bacterial reverse mutation test (OECD 471), one in vitro micronucleus test (OECD 487), and one sub-chronic 90-day toxicity study (OECD 408). In this last study, the NOAEL has been measured at 5000 mg/kg BW/day. Regarding allergenicity, no safety concern has been highlighted in a bioinformatics study. Therefore, the dried biomass of *G. sulphuraria* is well-characterized and compliant with European regulations.

The product is safe and devoid of significant allergic potential. The dried biomass does not present consequently any potential hazard to the European population in the conditions proposed by the applicant.