Summary of the application: Esterified propoxylated glycerol (EPG)

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Epogee, LLC submits this application for the approval of esterified propoxylated glycerol (EPG) as a novel food. 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.

EPG is a fat-like substance that resembles triglycerides in structure and appearance but has been modified to prevent or limit digestion when consumed, whereby the α-methyl group of the propylene glycol units sterically blocks access of lipase to the ester linkage. It is produced by esterification of propoxylated glycerol with fatty acids, followed by distillation and tocopherol addition.

EPG is intended for use in a range of food and beverage products, including but not limited to, flavoured and unflavoured fermented milk-based products, fats and oils, fine bakery wares, sauces, and desserts. it is intended for use by the general population.

Analytical data of several independent representative batches of EPG demonstrate that the manufacturing process results in a consistent final ingredient of >99.5% purity that meets the established specifications, and confirmed that any potential undesirable substances (heavy metals, microbial contaminants, 3-monochloropropanediol [3-MCPD], glycidyl fatty acid esters, dioxins and polychlorinated biphenyls, polycyclic aromatic hydrocarbons) are either undetectable or at negligible amounts in the final ingredient. Stability data demonstrate that EPG is stable for its proposed shelf-life when stored under real-time conditions.

A comprehensive battery of toxicology studies was conducted with batches of EPG that are representative of the ingredient intended to be commercially marketed, and in accordance with Good Laboratory Practice and appropriate internationally recognised test guidelines, where applicable. EPG was not systemically available in *in vivo* ADME studies and was confirmed as non-genotoxic both *in vitro* and *in vivo*. Several repeated dose toxicity studies (ranging from 90 days to 2 years) in rodent and non-rodent species, demonstrated the safety of EPG following subchronic and chronic exposure. EPG also showed no evidence of reproductive or developmental toxicity when administered over a single or multiple generations. These results are corroborated by several clinical studies conducted with healthy human volunteers, where consumption of EPG at daily amounts exceeding the estimated high-level intakes of EPG were well tolerated. Furthermore, as EPG does not contain protein, and none of the raw materials or processing aids used in the production process contain any of the allergens specified under Regulation (EU) No 1169/2011, the allergenic potential of EPG is negligible.

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