Safety evaluation of the food enzyme phospholipase D from the non-genetically modified Streptomyces netropsis strain DSM 40093

1 Report

Status Finished
EFSA question number EFSA-Q-2016-00536
Adopted 12-09-2025
Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme Phospholipase D from Streptomyces netropsis strain DSM 40093. Additional information requested from the applicant during the assessment process on 22 September 2022 and 15 December 2023 was received on 30 September 2023 and 13 September 2024, respectively. Following the request for additional data sent by EFSA on 22 September 2022, the applicant requested a clarification teleconference on 20 December 2022, after which the applicant provided additional data on 30 September 2023

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a [. . .] fermentation system with conventional process controls in place
Formulation Unknown
Downstream processing After completion of the fermentation, the cells of the production strain are [...] treated and separated from the fermentation broth by filtration. The filtrate containing the enzyme is further purified and concentrated, including an ultrafiltration step in which enzyme protein is retained, while most of the low molecular mass material passes the filtration membrane and is discarded. The enzyme is precipitated with [...] in the presenceof [...]. The solids are recovered by centrifugation, dried and then granulated to produce the food enzyme preparation.
Average TOS (w/w) 22.7 %
Average activity/TOS 16.5 U/mg TOS

3 EFSA tested impurities

Production strain and recombinant DNA The absence of viable cells of the production strain in the food enzyme was demonstrated.
Allergenicity the Panel considered that, under the conditions of use, a risk of allergic reactions upon dietary exposure to this food enzyme cannot be excluded, but that the likelihood is low
Antimicrobial resistance No antimicrobial activity was detected in any of the tested batches.
Antifoam agents /
Other /
Pathogens
Microbiological quality indicators
Metals
Coments LoDs: Pb = 1 mg/kg; As = 1 mg/kg; Cd = 1 mg/kg; Hg = 1 mg/kg.