



Safety evaluation of the food enzyme phospholipase D from the genetically modified *Streptomyces* *violaceoruber* strain pPDN

1 Report

Status Finished

EFSA question number [EFSA-Q-2016-00206](#)

Adopted 15-04-2026

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the phospholipase D from a genetically modified strain of *Streptomyces violaceoruber* (pPDN). Additional information was requested from the applicant during the assessment process on 22 September 2022 and received on 21 March 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 solid biomass is removed from the fermentation broth by filtration. The filtrate containing the enzyme is then further purified and concentrated, including an ultrafiltration step in which enzyme protein is retained, while most of the low molecular mass material passes the membrane and is discarded. Finally, the food enzyme was spray-dried prior to analysis

Average TOS (w/w) 81.1 %

Average activity/TOS 627.8 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. The absence of recombinant DNA in the food enzyme was demonstrated.



Allergenicity The Panel considered that under the intended 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 The presence of aflatoxins B1, B2, G1 and G2 was examined in the batch used for toxicological studies and were below the limits of detection (LoDs) of the applied analytical method

Pathogens

Microbiological quality indicators

Metals

Comments LoQs: Pb = 0.05 mg/kg; As = 0.75 mg/kg; Cd, Hg = 0.01 mg/kg each. LoD: aflatoxins (B1, B2, G1 and G2) = 1 µg/kg each.