

Safety evaluation of the food enzyme glucose oxidase from the non-genetically modified *Penicillium rubens* strain PGO 19–162

1 Report

Status Finished

EFSA question number [EFSA-Q-2016-00533](#)

Adopted 21-05-2025

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme glucose oxidase from *Penicillium rubens* strain PGO 19-162. Additional information was requested from the applicant during the assessment process on 4 May 2023 and received on 3 August 2023. The applicant provided also additional information as spontaneous submission on 10 February 2025.

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a submerged, batch 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 filtration membrane and is discarded.¹⁰

Average TOS (w/w) 1.9 %

Average activity/TOS 84.7 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, particularly for almond allergic individuals, cannot be excluded. However, the likelihood of such reactions will not exceed the risk of reactions after almond consumption

Antimicrobial resistance No antimicrobial activity was detected in any of the tested batches.

Antifoam agents /

Other The presence of ochratoxin A, aflatoxins (B1, B2, G1, G2), zearalenone, sterigmatocystin, T-2 toxin, roquefortine C and chrysogine was examined in three food enzyme batches and were below the limits of detection (LoD) of the applied analytical methods.

Pathogens

Microbiological quality indicators

Metals

Comments LoQs: Pb = 0.05 mg/kg; As = 3 mg/kg. LODs: ochratoxin A and aflatoxins (B1, B2, G1, G2) = 0.5 µg/kg each; zearalenone and T2-toxin = 50 µg/kg each; sterigmatocystin = 20 µg/kg; roquefortine C = 0.25 ppm; chrysogine = 9 ng/g.