

Safety evaluation of the food enzyme D-psicose 3-epimerase from the genetically modified *Escherichia coli* strain K-12 W3110-TKO CDX-088

1 Report

Status Finished

EFSA question number [EFSA-Q-2024-00310](#)

Adopted 11-09-2025

Previous authorisations The applicant has submitted a dossier in support of the application for authorisation of the food enzyme d-psicose 3-epimerase from *Escherichia coli* strain K-12 W3110-TKO CDX-088. Additional information, requested from the applicant during the assessment process on 26 March 2025, was received on 21 April 2025

2 Production method

Manufacturing The production strain is grown as a pure culture using a typical industrial medium in a submerged, [...] fermentation system with conventional process controls in place. [...] is added during fermentation to [...].

Formulation Unknown

Downstream processing After completion of the fermentation, the cells are harvested by centrifugation, resuspended and then mechanically disrupted by high-pressure homogenisation. Afterwards, the cell homogenate [...]. The solid biomass is removed by centrifugation. The supernatant 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. Finally, the enzyme solution is freeze-dried prior to analysis

Average TOS (w/w) 87.1 %

Average activity/TOS 116.9 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 /

Pathogens

Microbiological quality indicators

Metals

Comments LoQs: Pb = 0.005 mg/kg; As = 0.01 mg/kg; Cd = 0.005 mg/kg; Hg = 0.005 mg/kg. LoQ: IPTG = 125 mg/kg.