

ADOPTED: 7 May 2020

doi: 10.2903/j.efsa.2020.6145

Safety and efficacy of STABILFLOR[®] as a zootechnical feed additive for pigs for fattening

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Abstract

Following a request from the European Commission, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was asked to deliver a scientific opinion on the safety and efficacy of STABILFLOR[®] (zinc ethylenediaminetetraacetic acid (Zn-EDTA) and copper diammonium EDTA (Cu-EDTA) dried on chicory pulp and supplemented with zinc oxide and copper oxide), as a zootechnical additive for pigs. STABILFLOR[®] is intended to be used in feed for pigs for fattening at a minimum and maximum levels of 500 and 1,000 mg/kg complete feed, respectively. The Panel could not conclude on the safety of STABILFLOR[®] for pigs for fattening owing to the lack of adequate data. At the proposed used levels in feed the additive may exert antimicrobial activity in the gut microbiota. The use of the additive resulted neither in residues of Zn-EDTA, Cu-EDTA or EDTA nor on an increase in total zinc and copper deposition in edible tissues; Zn-EDTA and Cu-EDTA had not a genotoxic potential; the Panel concluded that STABILFLOR[®] at 1,000 mg/kg complete feed for pigs does not pose any concern to the safety of consumers. The handling of STABILFLOR[®] will lead to a copper exposure of the users that poses a risk by inhalation; the additive is not a skin irritant or a skin sensitiser but is a severe eye irritant. Regarding environmental safety, no concern was expected for the terrestrial compartment. A risk for groundwater was highlighted for Zn-EDTA. Due to the absence of data, the risk for the aquatic compartment could not be assessed. Only one efficacy study showed positive effects of STABILFLOR[®] in pigs for fattening at 1,000 mg/kg complete feed; a conclusion on the efficacy of STABILFLOR[®] could not be drawn. The minimum use level of 500 mg STABILFLOR[®]/kg complete feed was not tested.

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Keywords: zootechnical additives, gut flora stabilisers, STABILFLOR[®], zinc EDTA, copper diammonium EDTA, safety, efficacy

Requestor: European Commission

Question number: EFSA-Q-2017-00627

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Acknowledgements: The FEEDAP Panel wishes to thank the following for the support provided to this scientific output (in alphabetical order of the last name): Montserrat Anguita, Jaume Galobart, Paola Manini and Jordi Tarrés-Call.

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Suggested citation: EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), Bampidis V, Azimonti G, Bastos ML, Christensen H, Dusemund B, Kos Durjava M, Kouba M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Finizio A, Focks A, Gropp J, Mantovani A, Teodorovic I and López-Gálvez G, 2020. Scientific Opinion on the safety and efficacy of STABILFLOR® as a zootechnical feed additive for pigs for fattening. *EFSA Journal* 2020;18(6):6145, 2 pp. <https://doi.org/10.2903/j.efsa.2020.6145>

ISSN: 1831-4732

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