

ADOPTED: 2 April 2019

doi: 10.2903/j.efsa.2019.5693

Safety and efficacy of Levucell[®] SB (*Saccharomyces cerevisiae* CNCM I-1079) as a feed additive for turkeys for fattening

EFSA Panel on Additives and Products or Substances used in Animal Feed
(EFSA FEEDAP Panel),

Vasileios Bampidis, Giovanna Azimonti, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Maryline Kouba, Mojca Kos Durjava, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa, Ruud Woutersen, Montserrat Anguita, Jaume Galobart, Orsolya Holczknecht, Paola Manini, Jordi Tarrés-Call, Elisa Pettenati and Fabiola Pizzo

Abstract

Following a request from the European Commission, the EFSA 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 Levucell[®] SB when used in feed for turkeys for fattening. The additive is intended for use as a zootechnical additive (functional group: other additives) for the reduction of *Salmonella* contamination on carcasses through its decrease in faeces. In the context of a previous opinion, the identity of the strain was confirmed, and according to the Qualified Presumption of Safety (QPS) approach to safety assessment, it was presumed safe for the target species, consumers and the environment. Since no concerns are expected from other components of the additive, Levucell[®] SB is also considered safe for the target species, consumers and the environment. The additive is not a skin or eye irritant or a skin sensitiser. Considering the data on the dusting potential, the user can be exposed to the additive by inhalation when handling it. The additive in non-encapsulated form should be considered as a respiratory sensitiser. The coated formulation is not considered to pose a risk by inhalation. The efficacy of Levucell[®] SB for the same purpose was previously established in chickens for fattening. The FEEDAP Panel concluded that there was some evidence that the addition of Levucell[®] SB at 2×10^{10} CFU/kg feed has a potential to aid the reduction of carcass contamination with *Salmonella* spp. Since the mechanism of action of the additive can be reasonably assumed to be same, Levucell[®] SB can be presumed efficacious in turkeys for fattening at a dose of 2×10^{10} CFU/kg feed without the need for additional studies.

© 2019 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

Keywords: zootechnical additive, Levucell[®] SB, *Saccharomyces cerevisiae*, safety, QPS, turkeys for fattening

Requestor: European Commission

Question number: EFSA-Q-2018-00631

Correspondence: feedap@efsa.europa.eu

Panel members: Giovanna Azimonti, Vasileios Bampidis, Maria de Lourdes Bastos, Henrik Christensen, Birgit Dusemund, Maryline Kouba, Mojca Kos Durjava, Marta López-Alonso, Secundino López Puente, Francesca Marcon, Baltasar Mayo, Alena Pechová, Mariana Petkova, Fernando Ramos, Yolanda Sanz, Roberto Edoardo Villa and Ruud Woutersen.

Acknowledgements The Panel wishes to thank the following for the support provided to this scientific output: Lucilla Gregoretti and Rosella Brozzi. The Panel wishes to acknowledge all European competent institutions, Member State bodies and other organisations that provided data for this scientific output.

Suggested citation: EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Bampidis V, Azimonti G, de Lourdes Bastos M, Christensen H, Dusemund B, Kouba M, Kos Durjava M, López-Alonso M, López Puente S, Marcon F, Mayo B, Pechová A, Petkova M, Ramos F, Sanz Y, Villa RE, Woutersen R, Anguita M, Galobart J, Holczknecht O, Manini P, Tarrés-Call J, Pettenati E and Pizzo F, 2019. Scientific Opinion on the safety and efficacy of Levucell® SB (*Saccharomyces cerevisiae* CNCM I-1079) as a feed additive for turkeys for fattening. EFSA Journal 2019;17(4):5693, 7 pp. <https://doi.org/10.2903/j.efsa.2019.5693>

ISSN: 1831-4732

© 2019 European Food Safety Authority. *EFSA Journal* published by John Wiley and Sons Ltd on behalf of European Food Safety Authority.

This is an open access article under the terms of the [Creative Commons Attribution-NoDerivs](https://creativecommons.org/licenses/by/4.0/) License, which permits use and distribution in any medium, provided the original work is properly cited and no modifications or adaptations are made.



The EFSA Journal is a publication of the European Food Safety Authority, an agency of the European Union.



Table of contents

Abstract.....	1
1. Introduction.....	4
1.1. Background and Terms of Reference.....	4
1.2. Additional information.....	4
2. Data and methodologies.....	4
2.1. Data.....	4
2.2. Methodologies.....	5
3. Assessment.....	5
3.1. Characterisation of the additive and conditions of use.....	5
3.2. Safety.....	6
3.3. Efficacy.....	6
3.4. Post-market monitoring.....	6
4. Conclusions.....	6
Documentation provided to EFSA.....	6
Chronology.....	6
References.....	6
Abbreviations.....	7

1. Introduction

1.1. Background and Terms of Reference

Regulation (EC) No 1831/2003¹ establishes the rules governing the Community authorisation of additives for use in animal nutrition. In particular, Article 4(1) of that Regulation lays down that any person seeking authorisation for a feed additive or for a new use of a feed additive shall submit an application in accordance with Article 7.

The European Commission received a request from Danstar Ferment AG² for authorisation of the product Levucell® SB (*Saccharomyces cerevisiae* CNCM I-1079), when used as a feed additive for turkeys for fattening (category: zootechnical additives; functional group: other zootechnical additives – reduction of carcass contamination with *Salmonella* spp.).

According to Article 7(1) of Regulation (EC) No 1831/2003, the Commission forwarded the application to the European Food Safety Authority (EFSA) as an application under Article 4(1) (authorisation of a feed additive or new use of a feed additive). The particulars and documents in support of the application were considered valid by EFSA as of 25 November 2018.

According to Article 8 of Regulation (EC) No 1831/2003, EFSA, after verifying the particulars and documents submitted by the applicant, shall undertake an assessment in order to determine whether the feed additive complies with the conditions laid down in Article 5. EFSA shall deliver an opinion on the safety for the target animals, consumer, user and the environment and on the efficacy of the product Levucell® SB (*Saccharomyces cerevisiae* CNCM I-1079), when used under the proposed conditions of use (see Section 3.1).

1.2. Additional information

The additive Levucell® SB is a preparation of *S. cerevisiae* (CNCM I-1079).

Levucell SB® is currently authorised for use as a zootechnical additive in sows and weaned piglets³ (gut flora stabiliser) and in chickens for fattening and in minor poultry species (other zootechnical additive).⁴

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) produced some opinions on the safety and efficacy of Levucell® SB when used as a feed additive for weaned piglets and sows (EFSA FEEDAP Panel, 2016), chickens for fattening and minor poultry species (EFSA FEEDAP Panel, 2017a), and all pigs (EFSA FEEDAP Panel, 2019).

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier⁵ in support of the authorisation request for the use of Levucell® SB as a feed additive.

The FEEDAP Panel used the data provided by the applicant together with data from other sources, such as previous risk assessments by EFSA, to deliver the present output.

The European Union Reference Laboratory (EURL) considered that the conclusions and recommendations reached in the previous assessment are valid and applicable for the current application.⁶

¹ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

² Danstar Ferment AG, Switzerland represented in EU by Lallemand SAS, 19 Rue des Briquetiers, Blagnac, France.

³ Commission Implementing Regulation (EU) 2018/347 of 5 March 2018 concerning the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 as a feed additive for piglets and sows and amending Regulations (EC) No 1847/2003 and (EC) No 2036/2005 (holder of authorisation Danstar Ferment AG represented by Lallemand SAS). OJ L 67. 9.3.2018, p. 21.

⁴ Commission Implementing Regulation (EU) 2017/1905 of 18 October 2017 concerning an authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 as a feed additive for chickens for fattening and for minor poultry species for fattening (holder of authorisation Danstar Ferment AG represented by Lallemand SAS). OJ L 269. 19.10.2017, p. 30.

⁵ FEED dossier reference: FAD-2018-0050.

⁶ The full report is available on the EURL website: <https://ec.europa.eu/jrc/sites/jrcsh/files/finrep-fad-2010-0121-levucell.pdf>

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Levucell® SB is in line with the principles laid down in Regulation (EC) No 429/2008⁷ and the relevant guidance documents: Guidance on the identity, characterisation and conditions of use of feed additives (EFSA FEEDAP Panel, 2017b), Guidance on the characterisation of microorganisms used as feed additives or as production organisms (EFSA FEEDAP Panel, 2018a), Guidance on the assessment of the safety of feed additives for the target species (EFSA FEEDAP Panel, 2017c) and Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018b).

3. Assessment

The present opinion deals with the assessment of the safety and efficacy of Levucell® SB (*Saccharomyces cerevisiae* CNCM I-1079) as a zootechnical feed additive (functional group: other zootechnical additives – reduction of carcass contamination with *Salmonella* spp.) for turkeys for fattening.

3.1. Characterisation of the additive and conditions of use

The additive is composed of dried cells of the active agent *Saccharomyces cerevisiae* CNCM I-1079. The strain is deposited at the Collection Nationale de Cultures de Microorganismes (CNCM), France, with the accession number CNCM I-1079.⁸ The strain is not been genetically modified.

The additive is marketed in two forms:

- Levucell® SB20 a fine, granulated free-flowing powder with a minimum concentration of 2×10^{10} colony forming units (CFU)/g,
- Levucell® SB10 ME and Levucell® SB10 ME TITAN, coated or microencapsulated forms with a minimum concentration of 1×10^{10} CFU/g.

The additive under assessment has the same composition and method of manufacture as those considered in a previous application (EFSA FEEDAP Panel, 2016a). The applicant has provided results on five batches for each form on batch-to-batch variation, purity, particle size and dusting potential.

The content of the active agent was from 3 to 6 (mean: 4.1) $\times 10^{10}$ CFU/g and from 1.7 to 2.0×10^{10} CFU/g (mean: 1.8) for the non-encapsulated and coated formulations, respectively.⁹

The purity of the additive was evaluated only concerning the microbial parameters. Five batches of each formulation were tested for presence of viable yeasts, aerobic bacteria, solids, *Salmonella*, *Escherichia coli* and Enterobacteriaceae or coliforms, moulds.⁹ Based on the results, no concerns were identified.

Particle size distribution of three batches for each preparation of the product was measured by mechanical sieving. The highest percentage of particle of a size below 45 μm was 0.3% in the non-encapsulated product. No particle of a size below 355 μm was found in the coated product.¹⁰

The same batches analysed for particle size were also used for the evaluation of the dusting potential by the Stauber–Heubach method. Dusting potential for the non-encapsulated product produced an average of 0.6 g/m³ of dust, while the coated product was dust-free.¹¹

The identity and characterisation of the active agent was described in a previous opinion (EFSA FEEDAP Panel, 2016).

The additive is intended for use in feed for turkeys for fattening at the minimum recommended level of 1×10^9 CFU per kg feed.

⁷ Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives. OJ L 133, 22.5.2008, p. 1.

⁸ Technical dossier/Section II/Annex_II_4b.

⁹ Technical dossier/Section II/Annex_II_2.

¹⁰ Technical dossier/Section II/Annex_II_3b.

¹¹ Technical dossier/Section II/Annex_II_3c.

3.2. Safety

The species *Saccharomyces cerevisiae* is considered by EFSA to be suitable for the Qualified Presumption of Safety (QPS) approach to safety assessment (EFSA, 2007; EFSA BIOHAZ Panel, 2017). This approach requires the identity of the strain to be conclusively established.

In the context of a previous opinion (EFSA FEEDAP Panel, 2016), the identity of the strain was confirmed as *S. cerevisiae*. Accordingly, this strain is presumed safe for the target species, consumers of products from animals fed the additive and the environment. Since no concerns are expected from other components of the additive, Levucell® SB is also considered safe for the target species, consumers of products from animals fed the additive and the environment.

EFSA evaluated the safety of Levucell® SB (non-encapsulated form) for the user in a previous opinion and concluded that it is not a skin or eye irritant or a skin sensitiser (EFSA FEEDAP Panel, 2017a,b,c). Considering the data on dusting potential, the user can be exposed by inhalation. The additive in non-encapsulated form should be considered as a respiratory sensitiser. The coated formulation (Levucell® SB10 ME Titan) is not considered to pose a risk by inhalation.

The FEEDAP Panel considers that the new use requested by the applicant would not introduce hazards/risks not already considered in previous assessments.

3.3. Efficacy

The additive is intended for use in turkeys for fattening as a zootechnical additive (functional group: other additives) for the reduction of *Salmonella* contamination on carcasses through its decrease in faeces.

The efficacy of Levucell® SB for the same purpose was previously established in chickens for fattening. Based on five efficacy studies in chickens for fattening the FEEDAP Panel concluded that there is some evidence that the addition of Levucell® SB to diets has a potential to aid the reduction of carcass contamination with *Salmonella* spp. and so to improve the quality of poultry products. The effective dose appears to be 2×10^{10} CFU/feed (EFSA FEEDAP Panel, 2017a).

Since the mechanism of action of the additive can be reasonably assumed to be same, Levucell® SB can be presumed efficacious in turkeys for fattening at a dose of 2×10^{10} CFU/kg feed without the need for additional studies.

3.4. Post-market monitoring

The FEEDAP Panel considers that there is no need for specific requirements for a post-market monitoring plan other than those established in the Feed Hygiene Regulation¹² and Good Manufacturing Practice.

4. Conclusions

The additive is considered safe for turkeys for fattening, consumers of products from treated animals and the environment.

Levucell® is not a skin or eye irritant or a skin sensitiser. The additive in non-encapsulated form should be considered as a respiratory sensitiser. The coated formulation (Levucell® SB10 ME Titan) is not considered to pose a risk by inhalation.

The addition of the additive to diets for turkeys for fattening at a dose of 2×10^{10} CFU/kg feed can aid the reduction of carcass contamination with *Salmonella* spp..

Documentation provided to EFSA

- 1) Levucell SB for turkeys for fattening. July 2018. Submitted by Danstar Ferment AG, Switzerland represented in EU by Lallemand SAS.
- 2) Comments from Member States.

¹² Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

Chronology

Date	Event
27/07/2018	Dossier received by EFSA. Levucell SB for turkeys for fattening. Submitted by Danstar Ferment AG, Switzerland represented in EU by Lallemand SAS.
13/08/2018	Reception mandate from the European Commission
25/09/2018	Application validated by EFSA – Start of the scientific assessment
25/12/2018	Comments received from Member States
02/04/2019	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

References

- EFSA (European Food Safety Authority), 2007. Opinion of the Scientific Committee on a request from EFSA on the introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. *EFSA Journal* 2007;5(12):587, 16 pp. <https://doi.org/10.2903/j.efsa.2007.587>
- EFSA BIOHAZ Panel (EFSA Panel on Biological Hazards), 2017. Scientific Opinion on the update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA. *EFSA Journal* 2017;15(3):4664 <https://doi.org/10.2903/j.efsa.2017.4664>
- EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), 2016. Safety and efficacy of Levucell® SB (*Saccharomyces cerevisiae* CNCM I-1079) as a feed additive for weaned piglets and sows. *EFSA Journal* 2016;14(6):4478, 3 pp. <https://doi.org/10.2903/j.efsa.2016.4478>
- EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), 2017a. Safety and efficacy of Levucell® SB (*Saccharomyces cerevisiae* CNCM I-1079) as a feed additive for chickens for fattening and minor poultry species. *EFSA Journal* 2017;15(1):4674, <https://doi.org/10.2903/j.efsa.2017.4674>
- EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), 2017b. Guidance on the identity, characterisation and conditions of use of feed additives. *EFSA Journal* 2017;15(10):5023, 12 pp. <https://doi.org/10.2903/j.efsa.2017.5023>
- EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), 2017c. Guidance on the assessment of the safety of feed additives for the target species. *EFSA Journal* 2017;15(10):5021, 19 pp. <https://doi.org/10.2903/j.efsa.2017.5021>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2018a. Guidance on the characterisation of microorganisms used as feed additives or as production organisms. *EFSA Journal* 2018;16(3):5206, 24 pp. <https://doi.org/10.2903/j.efsa.2018.5206>
- EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), 2018b. Guidance on the assessment of the efficacy of feed additives. *EFSA Journal* 2018;16(5):5274, 25 pp. <https://doi.org/10.2903/j.efsa.2018.5274>
- EFSA FEEDAP Panel (EFSA Panel on additives and products or substances used in animal feed), 2019. Safety and efficacy of Levucell®SB (*Saccharomyces cerevisiae* CNCM I-1079) as a feed additive for all pigs. *EFSA Journal* 2019;17(1):5535, 7 pp. <https://doi.org/10.2903/j.efsa.2019.5535>

Abbreviations

CFU	colony forming unit
CNCM	Collection Nationale de Cultures de Microorganismes
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
QPS	Qualified presumption of safety
SCAN	Scientific Committee on Animal Nutrition