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Safety and efficacy of Levucell® SB (*Saccharomyces cerevisiae* CNCM I-1079) as a feed additive for all pigs

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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 suckling piglets, pigs for fattening and minor porcine species. Levucell® SB is the trade name for a feed additive based on viable cells of a strain *Saccharomyces cerevisiae* currently authorised as a zootechnical additive for weaned piglets, sows, chickens for fattening and minor poultry species for fattening. The applicant is now seeking authorisation as a zootechnical additive for use with all pigs. 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 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, including all pigs, consumers and the environment. Levucell® is not a skin or eye irritant or a skin sensitiser. Inhalation exposure is unlikely. Encapsulation used in the existing coated forms is not expected to introduce hazards for users. In previous opinions, Levucell® SB was found to have the potential to be efficacious in sows and weaned piglets at the dose of 1×10^9 colony forming units (CFU)/kg complete feedingstuffs. Since the dose proposed for use with all pigs is the same as that demonstrated to be effective in weaned piglets and sows, and it can be reasonably assumed that the mode of action is the same, the conclusion on efficacy for weaned piglets and sows can be extrapolated to all pigs. Therefore, the FEEDAP Panel concludes that Levucell® SB has the potential to be efficacious in all pigs at 1×10^9 CFU/kg feedingstuffs.

Keywords: zootechnical additive, Gut flora stabilisers, Levucell® SB, *Saccharomyces cerevisiae* CNCM I-1079, safety, QPS, pigs

Requestor: European Commission

Question number: EFSA-Q-2018-00473

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Note: Relevant information or parts of this scientific output have been blackened in accordance with the confidentiality requests formulated by the applicant pending a decision thereon by the European Commission. The full output has been shared with the European Commission, EU Member States and the applicant. The blackening will be subject to review once the decision on the confidentiality requests is adopted by the European Commission.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1831/2003[1] 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 Lallemand SAS[2] for authorisation of the product Levucell® SB (*Saccharomyces cerevisiae* CNCM I-1079), when used as a feed additive for piglets (suckling), pigs for fattening, minor porcine categories and minor porcine species (category: zootechnical additives; functional group: gut flora stabilisers).

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 16 July 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). EFSA issued one opinion on the safety and efficacy of this product for weaned piglets and sows (EFSA FEEDAP Panel, 2016a), one on the safety and efficacy for chickens for fattening and minor poultry species (EFSA FEEDAP Panel, 2016b) and one on its efficacy for weaned piglets (EFSA FEEDAP Panel, 2017).

The product is currently authorised as a zootechnical additive (functional group: gut flora stabilisers) for use with weaned piglets and sows,[3] and as a zootechnical additive (functional group: other zootechnical additives) for use with chickens for fattening and minor poultry species for fattening.[4]

2. Data and methodologies

2.1. Data

The present assessment is based on data submitted by the applicant in the form of a technical dossier[5] in support of the authorisation request for the use of Levucell® SB (*Saccharomyces cerevisiae* CNCM I-1079) as a feed additive.

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]

2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the safety and the efficacy of Levucell® SB (*Saccharomyces cerevisiae* CNCM I-1079) is in line with the principles laid down in Regulation (EC)

[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] Lallemand SAS. 137, 19 Rue des Briquetiers, BP 31702. 59700 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-2018-0030.
[6] The full report is available on the EURL website: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0121?search&form-return

No 429/2008[7] and the relevant guidance documents: Guidance on the assessment of the efficacy of feed additives (EFSA FEEDAP Panel, 2018).

3. Assessment

The additive Levucell® SB is a preparation consisting of dried cells of *S. cerevisiae* CNCM I-1079, intended for use as a zootechnical additive (gut flora stabiliser) in feed for all pigs.

3.1. Characterisation

Levucell® SB is marketed in three forms:

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

The additive under assessment has the same composition and method of manufacture as those considered in a previous application (EFSA FEEDAP Panel, 2016a). Therefore, data pertaining to composition, impurities, physical properties and stability submitted in the previous application dossier still apply.

The additive is intended for use in feed for all pigs at the minimum inclusion level of 1×10^9 CFU/kg feed.

3.2. Safety

3.2.1. Safety for the target species, consumers and the environment

The species *S. 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, 2016a), the identity of the strain was confirmed as *S. cerevisiae* CNCM I-1079. Accordingly, this strain is considered by EFSA to be suitable for the QPS approach to safety and 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.

3.2.2. Safety for the user

In a previous opinion (EFSA FEEDAP Panel, 2016a), Levucell® SB was found to be not a skin or eye irritant or a skin sensitiser. Inhalation exposure was considered unlikely. Encapsulation was not expected to introduce hazards for users. The use of the additive in all pigs is considered unlikely to introduce hazards for users of the product not already considered as part of the first assessment. Therefore, the conclusions reached in the previous assessment apply to the current application.

3.3. Efficacy

The efficacy of Levucell® SB for weaned piglets and sows has been established at the dose of 1×10^9 CFU/kg feedingstuffs (EFSA FEEDAP Panel, 2016a, 2017). The dose proposed for use with pigs for fattening, minor pig categories and minor porcine species is the same as that showed a potential to be effective in weaned piglets and sows, and it can be reasonably assumed that the mode of action is the same. Consequently, the conclusion on efficacy for weaned piglets and sows can be extrapolated to all pigs.

[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.

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 Regulation[8] and Good Manufacturing Practice.

4. Conclusions

The additive is composed of dried cells of *S. cerevisiae* CNCM I-1079 which fulfils the requirements of the QPS approach to the assessment of safety and no concerns are expected from other components of the additive. Consequently, Levucell SB® is considered safe for the target animals, including all pigs, consumers of products from treated animals and the environment.

Levucell® is not a skin or eye irritant or a skin sensitiser. Inhalation exposure is unlikely. Encapsulation used in the coated forms is not expected to introduce hazards for users.

Levucell® SB has the potential to be efficacious in all pigs at 1×10^9 CFU/kg feedingstuffs.

Documentation provided to EFSA

1) LEVUCELL® SB Saccharomyces cerevisiae CNCM I-1079 for pigs/*Suidae* species and categories, suckling piglets, pigs for fattening, minor pig categories (e.g. boars and gilts) and minor porcine species (growing/reproductive). May 2018. Submitted by Danstar Ferment AG.
2) Comments from Member States.

Chronology

Date	Event
16/5/2018	Dossier received by EFSA
4/6/2018	Reception mandate from the European Commission
16/7/2018	Application validated by EFSA – Start of the scientific assessment
30/10/2018	Comments received from Member States
28/11/2018	Opinion adopted by the FEEDAP Panel. End of the Scientific assessment

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[8] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene. OJ L 35, 8.2.2005, p. 1.

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Abbreviations

CFU	colony forming units
EURL	European Union Reference Laboratory
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed
QPS	Qualified Presumption of Safety