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## Efficacy of Levucell<sup>®</sup> SB (*Saccharomyces cerevisiae* CNCM I-1079) as a feed additive for weaned piglets

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### Abstract

Levucell<sup>®</sup> SB is a feed additive based on viable cells of a strain *Saccharomyces cerevisiae* marketed in three formulations: SB20 with a minimum concentration of  $2 \times 10^{10}$  CFU/g viable yeast cells and SB10 ME and SB Titan, both microencapsulated forms with a minimum concentration of  $1 \times 10^{10}$  CFU/g viable yeast cells. In 2014, EFSA was requested by the European Commission to re-evaluate the product when used as a zootechnical additive in feed for sows and weaned piglets. The safety of the additive for consumers, users, the environment and target animals and its efficacy for sows was established at that time. In that instance, the FEEDAP also concluded on the potential Levucell<sup>®</sup> SB to improve growth of piglets based on one study where supplementation of the additive was done at the recommended dose of  $2 \times 10^9$  CFU/kg feedingstuffs and two at  $1 \times 10^9$  CFU/kg feedingstuffs, and considered that the effective dose was  $2 \times 10^9$  CFU/kg feedingstuffs. Two additional feeding trials in weaned piglets receiving the additive at  $1 \times 10^9$  CFU/kg feedingstuffs are the subject of this assessment. Due to the high mortality, one of the studies was not considered. In the remaining study, the supplementation of Levucell<sup>®</sup> SB to weaned piglets at  $1 \times 10^9$  CFU/kg feed resulted in a significant improvement of feed to gain ratio. Taking into account the two trials from the initial application which showed significant effects at  $1 \times 10^9$  CFU/kg feed, the FEEDAP Panel concludes that Levucell<sup>®</sup> SB has the potential to improve performance of weaned piglets when added to feed at  $1 \times 10^9$  CFU/kg complete feedingstuffs. Results of the efficacy studies can be applied to any of the three available formulations when used to deliver the same dose.

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**Keywords:** Zootechnical additive, gut flora stabilisers, Levucell<sup>®</sup> SB, *Saccharomyces cerevisiae* CNCM I-1079, efficacy, piglets

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**Amendment:** An editorial correction was carried out that does not materially affect the contents or outcome of this scientific output. To avoid confusion, the older version has been removed from the EFSA Journal, but is available on request, as is a version showing all the changes made.

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## 1. Introduction

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

Regulation (EC) No 1831/2003<sup>1</sup> establishes the rules governing the Community authorisation of additives for use in animal nutrition and in particular, Article 9 defines the terms of the authorisation by the Community.

The applicant, Lallemand SAS, is seeking a Community authorisation of Levucell® SB (*Saccharomyces cerevisiae* CNCM I-1079) to be used as a feed additive for weaned piglets and sows (Table 1).

**Table 1:** Description of the substances

<b>Category of additive</b>	Zotechnical additive
<b>Functional group of additive</b>	Digestibility enhancers and gut flora stabilisers
<b>Description</b>	<i>Saccharomyces cerevisiae</i> CNCM I-1079
<b>Target animal category</b>	Weaned piglets and sows
<b>Applicant</b>	Lallemand SAS
<b>Type of request</b>	New opinion

In its opinion on the safety and efficacy of the product, adopted on 20 April 2016, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) of the European Food Safety Authority ("Authority"), has concluded that Levucell® SB is demonstrated to be efficacious in sows at a concentration of  $1 \times 10^9$  CFU/kg feedingstuffs and in weaned piglets at the dose of  $2 \times 10^9$  CFU/kg feedingstuffs.

On 5 May 2016, the Commission has received a letter from the applicant, requesting a change from the currently recommended dose of  $2 \times 10^9$  CFU/kg feedingstuffs to  $1 \times 10^9$  CFU/kg feedingstuffs. The additional efficacy study to reflect this proposed new recommended dose is sent to the Commission and the Authority by the applicant.

The Commission has received the additional efficacy study in piglets in anticipation of such a request for further consideration.<sup>2</sup>

In view of the above, the Commission asks the Authority to deliver a new opinion on the efficacy of the product composed of Levucell® SB (*Saccharomyces cerevisiae* CNCM I-1079) as a feed additive for weaned piglets based on the additional data submitted by the applicant.

### 1.2. Additional information

In 2016, the FEEDAP Panel was unable to conclude on the efficacy of Levucell® SB to improve performance of weaned piglets when supplemented at  $1 \times 10^9$  CFU/kg feedingstuffs, as proposed by the applicant and could only conclude at a higher dose (EFSA FEEDAP Panel, 2016). The applicant has now submitted additional data to support efficacy at the dose originally proposed.

## 2. Data and methodologies

### 2.1. Data

The present assessment is based on data submitted by the applicant in the form of additional information<sup>3</sup> to a previous application on the same product.<sup>4</sup>

### 2.2. Methodologies

The approach followed by the FEEDAP Panel to assess the efficacy of Levucell® SB is in line with the principles laid down in Regulation (EC) No 429/2008<sup>5</sup> and the relevant guidance documents:

<sup>1</sup> 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.

<sup>2</sup> In the course of the assessment the applicant submitted a second study.

<sup>3</sup> FEED dossier reference: FAD-2016-0041.

<sup>4</sup> FEED dossier reference: FAD-2010-0121.

<sup>5</sup> 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.

Guidance on zotechnical additives (EFSA FEEDAP Panel, 2012), and the Technical guidance: Tolerance and efficacy studies in target animals (EFSA FEEDAP Panel, 2011).

### 3. Assessment

The scope of this opinion is to assess the efficacy of Levucell® SB when used as a zotechnical additive (digestibility enhancer and gut flora stabiliser) in feed for weaned piglets at the dose of  $1 \times 10^9$  CFU/kg feedingstuffs.

Levucell® SB is the trade name for a feed additive based on viable cells of *Saccharomyces cerevisiae* CNCM I-1079. It is marketed in three formulations: Levucell® SB20 with a minimum concentration of  $2 \times 10^{10}$  CFU/g viable yeast cells and Levucell® SB10 ME and Levucell® SB Titan, both microencapsulated forms (which differ minimally owing to a slightly different drying process) with a minimum concentration of  $1 \times 10^{10}$  CFU/g viable yeast cells. The FEEDAP Panel considers that the results of efficacy studies can be applied to any of the three available formulations when used to deliver the same dose.

In 2014, the European Food Safety Authority (EFSA) was requested by the European Commission to re-evaluate Levucell® SB when used as a zotechnical additive (functional groups: digestibility enhancers and gut flora stabilisers) in feed for sows and weaned piglets (EFSA FEEDAP Panel, 2016). The safety of the additive for consumers, users, the environment and target animals and its efficacy for sows was established at that time. The dossier included six efficacy studies in weaned piglets aiming to demonstrate the potential of Levucell® SB to improve zotechnical performance of animals. However, three of them were rejected due to limitations in the design or reporting and only three could be considered. In two of these studies, supplementation of the additive was done at the recommended dose of  $1 \times 10^9$  CFU/kg feedingstuffs and in the third at  $2 \times 10^9$  CFU/kg feedingstuffs. Therefore, the FEEDAP Panel concluded on the potential of Levucell® SB to improve performance of weaned piglets when supplemented at  $2 \times 10^9$  CFU/kg feedingstuffs.

#### 3.1. Efficacy for weaned piglets<sup>6</sup>

The applicant has produced two new feeding trials in weaned piglets receiving the additive at  $1 \times 10^9$  CFU/kg feedingstuffs. The first of these studies could not be considered due to the high mortality observed and a strong indication of health disorders.

The second study is described in detail in the dossier.<sup>7</sup>

Mortality was low and not influenced by treatment. Piglets in both groups showed similar values for final weight and feed intake. However, piglets of the Levucell® SB group showed a significant better feed to gain ratio compared to control animals.

Taking into account the two trials from the initial application which showed significant effects at  $1 \times 10^9$  CFU/kg feed and the newly submitted study, the FEEDAP Panel concludes that Levucell® SB has the potential to improve performance of weaned piglets when added to feed at  $1 \times 10^9$  CFU/kg complete feedingstuffs.

### 4. Conclusions

The FEEDAP Panel considers that these conclusions on Levucell® SB can be applied to any of the three available formulations when used to deliver the same dose.

Levucell® SB has the potential to improve the performance of weaned piglets when supplemented at the dose of  $1 \times 10^9$  CFU/kg complete feedingstuffs.

### Documentation provided to EFSA

- 1) Application for the authorisation of Levucell® SB in sows and piglets. Additional efficacy on piglets to support recommended dose:  $1 \times 10^9$  CFU/kg feed. July 2016. Submitted by Lallemand S.A.S.
- 2) Application for the authorisation of Levucell® SB for weaned piglets and sows under Article 29 of Regulation 178/20052. Supplementary information. November 2016. Submitted by Lallemand

<sup>6</sup> This section has been edited following the provisions of Article 8(6) and Article 18 of Regulation (EC) No 1831/2003.

<sup>7</sup> Technical dossier/Supplementary information February 2017/Annexes 3-8.

## References

- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2011. Technical guidance: tolerance and efficacy studies in target animals. EFSA Journal 2011;9(5):2175, 15 pp. <https://doi.org/10.2903/j.efsa.2011.2175>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012. Guidance for the preparation of dossiers for zootechnical additives. EFSA Journal 2012;10(1):2536, 14 pp. <https://doi.org/10.2903/j.efsa.2012.2536>
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2016. Scientific opinion on the safety and efficacy of Levucell® SB (*Saccharomyces cerevisiae* CNCM I-1079) as a feed additive for weaned piglets and sows]. EFSA Journal 2016;14(5):4478, 3 pp. <https://doi.org/10.2903/j.efsa.2016.4478>

## Abbreviations

ADG	average daily gain
CFU	colony forming unit
FEEDAP	EFSA Panel on Additives and Products or Substances used in Animal Feed