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

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

#### Abstract

Levucell<sup>®</sup> SB is the trade name for a feed additive based on viable cells of a strain *Saccharomyces cerevisiae*. *Saccharomyces cerevisiae* is considered by EFSA to be suitable for the Qualified Presumption of Safety (QPS) approach to establish safety for the target species, consumers and the environment. The identity of the strain present in the additive was established. Accordingly, this strain is presumed safe for the target species, consumers of products from animals fed the additive and the environment. Based on the data provided, the formulation Levucell<sup>®</sup> SB20, the uncoated form, is not a skin or eye irritant or a skin sensitiser. Inhalation exposure is unlikely. Encapsulation used in two other forms (Levucell<sup>®</sup> ME10 and Levucell<sup>®</sup> ME Titan) is not expected to introduce hazards for users. In four studies conducted in sows, the supplementation of Levucell<sup>®</sup> SB in the sows' feed at the recommended dose increased the daily weight gain of piglets. Consequently, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) concluded that Levucell<sup>®</sup> SB has the potential to be efficacious in sows at the dose of  $1 \times 10^9$  colony-forming unit (CFU)/kg feed. The results in the studies done in weaned piglets showed that the supplementation of Levucell<sup>®</sup> SB in the feed at the recommended dose resulted in a statistically significant improvement on the feed to gain ratio in two studies and in an improvement of the final body weight (and average daily weight gain) in another study. The FEEDAP Panel concluded that Levucell<sup>®</sup> SB has the potential to be efficacious in weaned piglets at the dose of  $2 \times 10^9$  CFU/kg feed.

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**Keywords:** Levucell SB, *Saccharomyces cerevisiae* CNCM I-1079, safety, efficacy, QPS, piglets, sows

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## Summary

Following a request from 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 the product Levucell<sup>®</sup> SB as feed additive for piglets and sows. Levucell<sup>®</sup> SB is the trade name for a feed additive based on viable cells of a strain of *Saccharomyces cerevisiae*. The additive is available in three solid formulations (SB20, SB10 ME and SB Titan, the last two are encapsulated forms) and is intended for use in feed for sows to have a benefit in piglets at  $1 \times 10^9$  colony-forming unit (CFU)/kg feed and for weaned piglets at  $2 \times 10^9$  CFU/kg feed.

*Saccharomyces cerevisiae* is considered by the European Food Safety Authority (EFSA) to be suitable for the Qualified Presumption of Safety (QPS) approach to establish safety for the target species, consumers and the environment. The identity of the strain present in the additive, *S. cerevisiae* (Collection Nationale de Cultures de Microorganismes (CNCM) I-1079), was established. Accordingly, this strain is presumed safe for the target species, consumers of products from animals fed the additive and the environment.

Based on the data provided, the formulation Levucell<sup>®</sup> SB20, the uncoated form, is not a skin or eye irritant or skin sensitiser. Inhalation exposure is unlikely. Encapsulation used in two other forms (Levucell<sup>®</sup> ME10 and Levucell<sup>®</sup> ME Titan) is not expected to introduce hazards for users.

In four studies conducted in sows, the supplementation of Levucell<sup>®</sup> SB in the sows' feed at the recommended dose increased the daily weight gain of piglets. Consequently, the FEEDAP Panel concluded that Levucell<sup>®</sup> SB has the potential to be efficacious in sows at the dose of  $1 \times 10^9$  CFU/kg feed. The results in the studies done in weaned piglets showed that the supplementation of Levucell<sup>®</sup> SB in the feed at the recommended dose resulted in a statistically significant improvement on the feed to gain ratio in two studies and in an improvement of the final body weight (and average daily weight gain) in another study. The FEEDAP Panel concluded that Levucell<sup>®</sup> SB has the potential to be efficacious in weaned piglets at the dose of  $2 \times 10^9$  CFU/kg feed. The different forms of the additive are considered to be equivalent when used to deliver the same dose.