

## SCIENTIFIC OPINION

### **Efficacy of the product Levucell SC20/Levucell SC10ME (*Saccharomyces cerevisiae*) as feed additive for leisure horses<sup>1</sup>**

#### **Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed**

(Question No EFSA-Q-2008-472)

**Adopted on 1 April 2009**

#### **PANEL MEMBERS**

Georges Bories, Paul Brantom, Joaquim Brufau de Barberà, Andrew Chesson, Pier Sandro Cocconcelli, Bogdan Debski, Noël Dierick, Jürgen Gropp, Ingrid Halle, Christer Hogstrand, Joop de Knecht, Lubomir Leng, Sven Lindgren, Anne-Katrine Lundebye Haldorsen, Alberto Mantovani, Miklós Mézes, Carlo Nebbia, Walter Rambeck, Guido Rychen, Atte von Wright and Pieter Wester

#### **SUMMARY**

Following a request from the European Commission, the European Food Safety Authority (EFSA) was asked to deliver a scientific opinion on the efficacy of the product Levucell SC20/Levucell SC10ME (*Saccharomyces cerevisiae*) for use as a feed additive for leisure horses.

Levucell SC20/Levucell SC10ME is a preparation of dried cells of *Saccharomyces cerevisiae* (CNCM I-1077). It is intended for use as a zootechnical additive in feed for leisure horses at a dose of  $3 \times 10^9$  CFU kg<sup>-1</sup> of complete feedingstuffs.

In its previous opinion on Levucell SC20/Levucell SC10ME for leisure horses, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) was not able to conclude on the efficacy of the preparation because of insufficient evidence provided by the company. The applicant has now provided an additional study aiming to demonstrate that the effect of Levucell SC20 for leisure horses corresponds to that for other ruminants, e.g. increase of fibre digestibility. Thus, the current opinion focuses on the assessment of that new study.

Evidence that Levucell SC20 is able to produce a significant improvement on fibre digestion was shown in one experiment in adult horses. This effect was consistent with the microbiological analyses of faecal samples, which showed a significant increase in gut cellulolytic bacteria associated with Levucell SC20 supplementation.

---

<sup>1</sup> For citation purposes: Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on a request from the European Commission on efficacy of the product Levucell SC20/Levucell SC10ME (*Saccharomyces cerevisiae*) as feed additive for leisure horses. *The EFSA Journal* (2009) 1040, 1-7

This product has been authorised for use in dairy cows, cattle for fattening, lambs, dairy goats and dairy ewes. The FEEDAP Panel considers that evidence has been provided to show that the effect of *S. cerevisiae* in horses is similar to that observed in ruminants. Therefore, the FEEDAP Panel concludes that the efficacy of Levucell SC 20 has been demonstrated in adult leisure horses.

**Key words:** zootechnical additive, micro-organism, yeast, *Saccharomyces cerevisiae*, Levucell SC20/Levucell SC10ME, leisure horses, efficacy, mode of action

**TABLE OF CONTENTS**

Panel Members .....	1
Summary .....	1
Table of Contents .....	3
Table of Contents .....	3
Background as provided by EC.....	4
Terms of reference as provided by EC .....	4
Acknowledgements .....	4
Assessment .....	5
1. Introduction .....	5
2. Efficacy.....	5
Conclusions and Recommendations.....	7
Documentation provided to EFSA .....	7
References .....	7

## BACKGROUND AS PROVIDED BY EC

Regulation (EC) No 1831/2003<sup>2</sup> establishes rules governing the Community authorisation of additives for use in animal nutrition and in particular defines the conditions that a substance/product should meet to be granted authorisation.

The company Lallemand is seeking an authorisation as a feed additive within category of “zootechnical additives”, functional group “other zootechnical additives”, of a preparation of *Saccharomyces cerevisiae* (Levucell SC 20/ SC10ME, Table 1).

Table 1.

Product category	Zootechnical additives: other zootechnical additives
Trade name	Levucell SC20/Levucell SC10ME
Description	<i>Saccharomyces cerevisiae</i> CNCM I-1077
Target animal category	Leisure horses
Applicant	Lallemand
Type of request	New authorisation

The EFSA in its opinion adopted on 12 September 2006 (Opinion of the Scientific Panel on Additives and Products or Substances used in Animal Feed on the safety and efficacy of the product Levucell SC20/Levucell SC10ME, a preparation of *Saccharomyces cerevisiae*, as a feed additive for leisure horses) was not able to decide conclusively on the efficacy of the preparation because of lack of data provided by the company.

Therefore, the Commission gave the possibility to the company to submit complementary information to complete the assessment.

The Commission has received a supplementary dossier from the applicant, Lallemand, containing new data on the efficacy of Levucell SC20/Levucell SC10ME for leisure horses. The data generated by the company and included in the above mentioned supplementary dossier have been sent directly to the Authority.<sup>3</sup>

## TERMS OF REFERENCE AS PROVIDED BY EC

In view of the above, the Commission asks the European Food Safety Authority to deliver an opinion on the efficacy of this active agent under the proposed conditions of use.

## ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank the members of the Working Group on Micro-organisms for the preparation of this opinion.

<sup>2</sup> OJ L 268, 18.10.2003, p.29

<sup>3</sup> Dossier reference: FAD-2008-0038

## ASSESSMENT

### 1. Introduction

The additive Levucell SC20/Levucell SC10ME is a preparation of dried cells of *Saccharomyces cerevisiae* (CNCM I-1077). It is intended for use in feed for leisure horses at a dose of  $3 \times 10^9$  CFU kg<sup>-1</sup> of complete feedingstuffs as a zootechnical additive (functional group: other zootechnical additives).

This product has been authorised for use in dairy cows and cattle for fattening,<sup>4</sup> lambs,<sup>5</sup> dairy goats and dairy ewes.<sup>6</sup>

The Scientific Committee on Animal Nutrition (SCAN) issued an opinion on the safety of this product for beef and dairy cattle, including safety for the user, the consumer and the environment (EC, 1997, updated 2003). The FEEDAP Panel has issued several opinions on the safety and efficacy of this product: one for dairy goats and dairy ewes (EFSA, 2006a), one for leisure horses (EFSA, 2006b) and one for lambs for fattening (EFSA, 2008).

In its previous opinion on Levucell SC20/Levucell SC10ME for leisure horses, the FEEDAP Panel was not able to conclude on the efficacy of the preparation because of insufficient evidence provided by the applicant. In particular, the FEEDAP Panel concluded that *'In one efficacy study, the differences in weight gain, despite showing significant effects (P < 0.05) in favour of the Levucell-treated group, are not convincing because of the low weight gain of the control and the housing-treatment interaction.'*

The opinion also stated that *'The FEEDAP Panel considers that the effect of S. cerevisiae in a hindgut fermenter, such as the horse, is likely to be similar to that seen in ruminants, where there is evidence of an effect on fibre digestion. Although there was a small but significant difference in body weight gain during the experiment, which may reflect better fibre digestion, this was not directly demonstrated. Consequently, the FEEDAP Panel, in the absence of evidence of a similar mode of action, cannot conclude on the efficacy of the product.'*

The applicant has provided an additional study aiming to demonstrate that the effect of Levucell SC20/Levucell SC10ME for leisure horses corresponds to the one seen in ruminants, e.g. increase of fibre digestibility. Thus, the current opinion focuses on the assessment of that new study.

### 2. Efficacy

With the aim of demonstrating the efficacy of Levucell SC20 for horses, one trial was provided.<sup>7</sup> Six adult horses (initial ages 4–18 years), whose average weight at the start of the trial was  $511 \pm 28$  kg, were individually housed in stalls equipped with feeding troughs and bedded with wood shavings to avoid uncontrolled ingestion of vegetable matter such as straw. Animals were fed a basal diet consisting of feedstuff concentrate (35 % of the total daily feed) supplemented with grass hay (65 %). The feedstuff concentrate contained corn, barley, lucerne, mineral mix, flax seed and cane molasses.

The experimental design was a 3 x 3 Latin square (three groups of two horses; three treatments). The treatments were, respectively, control and supplementation with Levucell SC20 at doses of  $2 \times 10^{10}$  CFU head<sup>-1</sup> day<sup>-1</sup> and  $6 \times 10^{10}$  CFU head<sup>-1</sup> day<sup>-1</sup>.

<sup>4</sup> OJ 195, 27.7.2005, p. 6

<sup>5</sup> OJ L 340, 19.12.2009, p. 38

<sup>6</sup> OJ L 64, 2.3.2007, p. 26

<sup>7</sup> Technical dossier/Annex 1 Trial Report

In the trial, the additive was top-dressed onto the morning concentrate. The two doses used ( $2 \times 10^{10}$  and  $6 \times 10^{10}$  CFU head<sup>-1</sup> day<sup>-1</sup>), based on the expected daily feed intake of 6.7 kg and on the microbiological analysis of the additive, can be translated into calculated doses of approximately  $3 \times 10^9$  and  $1 \times 10^{10}$  CFU kg<sup>-1</sup> feed.

All the horses were fed the control diet for a seven-day transitional period preceding the initiation of the study. This was followed by three successive experimental 28-day periods, each consisting of three sub-periods: 14 days of adaptation to the treatment doses, seven days of measurements and seven days of wash-out.

The end points focussed on the measurement of apparent digestibility of dry matter and fibre, on faecal pH and analysis of faecal microbiota. The quantity of feed refused was measured to determine the exact quantity of dry matter ingested. Faeces excreted were weighed each day. The dry matter and the proportions of fibre fractions (NDF, ADF and acid detergent lignin ADL) were determined on each sample. On day seven of each experimental period, faeces were collected directly from the rectum of each horse four hours after the morning meals. The pH was determined immediately after collection. Those faecal samples were analysed for total anaerobes, cellulolytic bacteria, streptococci, lactobacilli and lactic acid utilising bacteria. Statistical analyses were carried out using one-way ANOVA.

The experiment showed a significant treatment-related improvement of dry matter digestibility, largely attributable to an increase in apparent fibre digestion (Table 2). A significant effect was observed at the calculated recommended dose ( $3 \times 10^9$  CFU kg<sup>-1</sup> feed) and at a higher dose.

Table 2. **Effect of Levucell SC 20 on dry matter and fibre fractions digestibility**

Levucell	DM <sup>1</sup>	NDF <sup>2</sup>	ADF <sup>3</sup>
0	66.2 <sup>a</sup>	49.5 <sup>A</sup>	42.8 <sup>A</sup>
$2 \times 10^{10}$ CFU day <sup>-1</sup> ( $3 \times 10^9$ CFU kg <sup>-1</sup> feed)	69.9 <sup>b</sup>	52.0 <sup>B</sup>	45.6 <sup>B</sup>
$6 \times 10^{10}$ CFU day <sup>-1</sup> ( $1 \times 10^{10}$ CF kg <sup>-1</sup> feed)	70.5 <sup>b</sup>	52.3 <sup>B</sup>	45.0 <sup>B</sup>

Different superscripts indicate significant differences at A,B ( $P < 0.01$ ) and a,b ( $P < 0.05$ )

<sup>1</sup> Dry matter

<sup>2</sup> Neutral detergent fibre

<sup>3</sup> Acid detergent fibre

Microbiological analysis of faecal samples revealed a significant increase ( $P < 0.01$ ) of total anaerobes and cellulolytic bacteria during the experimental periods of Levucell SC20 supplementations. The counts of other bacterial groups were not affected by treatment, with the exception of the expected higher numbers of yeast cells.

## CONCLUSIONS AND RECOMMENDATIONS

### CONCLUSIONS

Evidence that Levucell SC20 is able to produce a beneficial effect on fibre digestibility was demonstrated in one experiment in adult horses. A demonstration of the effect is also provided by the microbiological analyses of faecal samples, which showed a significant increase in gut cellulolytic bacteria associated with Levucell SC20 supplementation.

This product has been authorised for use in dairy cows, cattle for fattening, lambs, dairy goats and dairy ewes. The FEEDAP Panel considers that evidence has been provided to show that the effect of *S. cerevisiae* on fibre digestion in horses is similar to that observed in ruminants. Therefore, the FEEDAP Panel concludes that the efficacy of Levucell SC20 as a digestibility enhancer is demonstrated in adult leisure horses. The FEEDAP Panel extends the above conclusions to both forms of Levucell SC.

### RECOMMENDATIONS

It is recommended that the product is categorised under the functional groups digestibility enhancers and gut flora stabilisers.

### DOCUMENTATION PROVIDED TO EFSA

1. Application for the use of Levucell SC 20 (*Saccharomyces cerevisiae* CNCM I-1077) in leisure horses (FAD-2005-0018). Submission of supplementary efficacy data. July 2008. Submitted by Lallemand.

### REFERENCES

- EC (European Commission), 1997, updated 2003. Opinion on the use of certain micro-organisms as additives in feedingstuffs.  
<[http://ec.europa.eu/food/fs/sc/scan/out93\\_en.pdf](http://ec.europa.eu/food/fs/sc/scan/out93_en.pdf)>
- EFSA (European Food Safety Authority), 2006a. Opinion of the Panel on additives and products or substances used in animal feed (FEEDAP) on the safety and efficacy of the product “Levucell SC20/Levucell SC10ME”, a preparation of *Saccharomyces cerevisiae*, as a feed additive for dairy goats and dairy ewes in accordance with Regulation (EC) No 1831/2003.  
<[http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620782934.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620782934.htm)>
- EFSA (European Food Safety Authority), 2006b. Opinion of the Panel on additives and products or substances used in animal feed (FEEDAP) on the safety and efficacy of the product “Levucell SC20/Levucell SC10ME”, a preparation of *Saccharomyces cerevisiae*, as a feed additive for leisure horses.  
<[http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1178620782659.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620782659.htm)>
- EFSA (European Food Safety Authority), 2008. Opinion of the Panel on additives and products or substances used in animal feed (FEEDAP) on the Safety and efficacy of Levucell SC20/Levucell SC10ME, a preparation of *Saccharomyces cerevisiae*, as feed additive for lambs for fattening.  
<[http://www.efsa.europa.eu/cs/BlobServer/Scientific\\_Opinion/feedap\\_op\\_ej772\\_levucell\\_en.pdf?ssbinary=true](http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/feedap_op_ej772_levucell_en.pdf?ssbinary=true)>