EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions
C2 - Management of scientific committees; scientific co-operation and networks

EVALUATION OF THE EFFICACY OF MICRO-ORGANISM PRODUCT « LEVUCELL® SB 20» (*SACCHAROMYCES CEREVISIAE* C.N.C.M. I-1079)

(adopted on 2 December 2002)

1. BACKGROUND

The product "Levucell® SB 20" (*Saccharomyces cerevisiae* C.N.C.M. I-1079), is already provisionally authorised for the use as feed additive for the animal category "Sows" and for the category "Piglets" (first authorisation: Commission Regulation EC No 1436/98) until 30 June 2004.

The product was assessed by SCAN for safety and is listed in annex of the SCAN report on the use of certain micro-organisms as additives in feedingstuffs (updated 22 March 2001).

The Commission received a request for a permanent Community authorisation for this animal category under the conditions set out in the following table:

Table 1

No.	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content
					CFU/kg of complete feedingstuff	
Micro-organisms						
3	*Saccharomyces cerevisiae* CNCM I-1079	Preparation of *Saccharomyces cerevisiae* containing a minimum of : 2 x 10^{10} CFU/g additive	Piglets pre-weaning and post-weaning until 30 kg	-	2 x 10^9	6 x 10^9

2. TERMS OF REFERENCE

The Scientific Committee for Animal Nutrition (SCAN) is requested to advise the Commission on the efficacy of the product "Levucell® SB 20" when used as a feed additive in feedingstuffs under the conditions proposed by the Company (see table 1).

3. OPINION

Levucell® SB20 is composed of approximately 94% by weight of dried cells of *Saccharomyces cerevisiae* I-1079 (80% by weight viable and 14 % non-viable), 1% sorbitane monostearate (E 491) (used as a surfactant and emulsifying agent) and 5% residual water. The guaranteed minimal concentration of viable yeast cells is 2 x 10^{10} cfu per gram of the additive.

Levucell® SB20 has previously been accepted by SCAN as safe for use as a feed additive with piglets and sows. SCAN is not aware of recent information indicating a need for a re-evaluation of the Opinion on the safety of the product[1]. Therefore this Opinion deals only with issues related with the efficacy of the product for piglets.

3.1. Stability of the product

The stability of the product has been thoroughly tested under a variety of different conditions. The results show that the additive contains at least the guaranteed minimum of viable yeast cells after 14 months of storage in its commercial packaging at ambient temperatures. In premixes the additive is stable for at least eight months under normal packaging conditions when the humidity of the carrier is less than 6%. In mixed meal feeds it is stable for at least 4.5 months and at least four months in pelleted feeds.

The temperature is important for the viability of the yeast. Very few viable cells remained after storage at 65 °C, whereas the viability of the cells was high after storage at 40 °C.

3.2. Efficacy for piglets

The efficacy of Levucell® SB20 has been tested in seven different trials involving a total of 3534 piglets. The first two trials were conducted in 1994/1995 (no. 6 and 7), the remaining in 2000/2001 (trials 1 to 5). The numbers refer to the summary table in volume 2 of the dossier. The doses used, the number of animals, the treatment periods and the performance of the piglets in the various trials are shown in Table 2. Mortality rate was also investigated.

Levucell® SB20 improved average daily gain significantly ($p<0.05$) in four of the seven trials and feed conversion ration was improved significantly in two trials. Mortality rate was significantly improved in one of the trials (trial 6). In the other trials mortality rate was not significantly different between the treatments.

In two of the trials showing significant improvement of daily gain (trial 6 and 7) the dose used was three-fold higher than the minimal dose requested for

---

[1] Report on the use of certain micro-organisms as additives in feedingstuffs (expressed, 26 september 1997; updated 30 september 1998)

approval (2 x 10^9 per kg feed). SCAN has recommended that efficacy should be demonstrated with the minimum recommended dose[2]. Thus, significant effects on daily gain have only been shown in two trials with animals fed the minimal required dose. However, the dose range recommended is very narrow and within the margin of error expected when numbers of viable organisms are determined. Consequently, SCAN considers that, in this case, data from the groups given the highest recommended dose are acceptable even if the dose is above the minimum dose requested for approval.

Table 2. Effect of Levucell® SB20 on average daily gain and feed conversion ratio in piglets.

Trial	Doses cfu/g	No. of piglets	Duration (days)	Start weight (kg)	Final weight (kg)	Average daily gain (g)	Feed conversion ratio
1	Control	272	45	9,2	31,9	440	1,57
	$2x10^9$	270		9,5	34,5	**476***	1,47
	$6x10^9$	271		9,2	33,3	462	1,56
2	Control	150	48	7,3	28,9	450	1,74
	$2x10^9$	148		7,3	29,1	453	**1,63***
3	Control	72	35	7,0	15,1	232	1,59
	$2x10^9$	71		6,9	16,3	**268****	1,50
4	Control	56	35	5,0	16,5	327	1,26
	$2x10^9$	56		5,0	17,0	343	1,27
	$6x10^9$	56		5,0	17,0	356	1,28
5	Control	40	46	7,7	27,5	432	1,77
	$6x10^9$	40		7,7	28,5	451	1,78
6	Control	611	33	7,9	18,7	366	1,67
	$6x10^9$	620		8,0	19,9	**379****	**1,56***
7	Control	400	33	7,9	21,4	430	1,64
	$6x10^9$	401		8,1	22,3	**445****	1,57

*P<0.05; **P<0.01

3.3. Conclusion

Based on these results SCAN considers that addition of Levucell® SB20 can improve the performance of piglets. The efficacy of Levucell® SB20 for use in piglets at doses between $2x10^9$ and $6x10^9$ cfu/kg feed is satisfactorily documented and therefore demonstrated.

[2] Guidelines for the assessment of additives in feedingstuffs Part II: enzymes and micro-organisms adopted on 1rst October 2001