



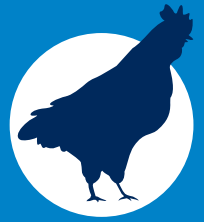
Vaxsafe® IBD

(Strain V877)



Features of Vaxsafe[®] IBD (Strain V877)

- Single dose for broiler chickens
- Safe for chickens from 14 days of age
- Protects against immuno-suppressive and virulent IBD viruses
- Limited bursal atrophy without immunosuppression
- Improves broiler performance



Safety Studies

Pathogenicity and Immunosuppression

Vaxsafe[®] IBD can be classified as an 'intermediate plus' vaccine. Pathogenicity testing was carried out in SPF chickens and included examination of the lymphoid tissues to determine the effect of vaccination on the immune system. Additional tests were undertaken to determine the extent of any immunosuppressive effect of Vaxsafe[®] IBD by examining the response in chickens vaccinated against Newcastle disease (ND) after previous vaccination with Vaxsafe[®] IBD. Vaxsafe[®] IBD was compared with three other commercial 'intermediate' or 'intermediate plus' IBD vaccines. The results of these tests indicated that vaccination with Vaxsafe[®] IBD caused a significant decrease in the bursa weight to body weight ratio, but no significant depression in the response to subsequent ND vaccination (Table 1). The degree of bursal atrophy observed was consistent with that described for moderately virulent IBD viruses, sometimes classified as intermediate-plus.

Table 1. Comparative bursa weight to body weight ratios and ND Haemagglutination Inhibition (HI) antibody responses of chickens vaccinated with one of four different IBD vaccines prior to vaccination with ND vaccine

IBD Vaccine	Bursa weight to body weight ratio (x 1000)	Geometric Mean ND HI titre (log ₂)
Vaxsafe [®] IBD	1.52*	21.19
Vaccine A	1.05*	14.98
Vaccine B	1.57*	18.88
Vaccine C	1.14*	9.44*
Nil	4.15	22.25

* Significantly different (p<0.05) to control group

Reversion to Virulence

Vaxsafe[®] IBD, a non-attenuated vaccine, does not increase in pathogenicity after 10 rapid passages in SPF chickens.

Field Safety Studies

Over 1.3 million broiler chickens, vaccinated with Vaxsafe[®] IBD at different doses (virus titres), were observed for evidence of adverse effects. Their performance was also measured against the broiler company's performance parameters. This study found that there were no adverse effects from Vaxsafe[®] IBD and the vaccinated flocks performed to, or exceeded, the relevant company standards and comparable unvaccinated flocks (Table 2). The study also demonstrated that Vaxsafe[®] IBD could be administered in the presence of IBD maternal antibody with a resulting reduction in broiler mortality and improvement in performance.

Table 2. Productivity data during grow-out and at slaughter age from 54 broiler flocks vaccinated and not vaccinated with Vaxsafe[®] IBD

Productivity Parameter	Vaccinated with Vaxsafe [®] IBD	Not Vaccinated
Body weight at 21 days (Kg)	0.83*	0.80
% mortality to 28 days	2.21*	2.83
% mortality to slaughter age	4.79*	6.87
Performance Index Factor (PIF)	247	245

* Significantly different (p<0.05)



Product Development

Infectious Bursal Disease (IBD) virus, strain V877 was first isolated at the NSW Department of Agriculture Veterinary Research Station, Glenfield in 1977. In 1998 BIOPROPERTIES Pty Ltd acquired the virus strain from NSW Agriculture in order to develop a non-attenuated vaccine suitable for use in broilers. Vaxsafe® IBD was registered in 2004. The finished product consists of a freeze-dried suspension of live IBD virus in SPF embryo homogenate. It is presented in 1000 & 2000 dose glass vials with a tear-off aluminium crimped cap. Safety and efficacy have been confirmed by a number of laboratory scale and field use studies.



Efficacy Studies

Onset of Immunity

Dose response studies have confirmed that Vaxsafe® IBD rapidly stimulates the production of specific antibody with protective levels being reached within 7 days of vaccination (Fig 1).

Duration of Immunity

Laboratory studies have demonstrated that vaccination with Vaxsafe® IBD will induce high and persistent levels of IBD antibody. Because of the established high correlation between IBD ELISA antibody levels and protection, all efficacy studies were undertaken without virulent challenge virus.

Response in the Presence of IBD Maternal Antibody

Vaxsafe® IBD can break through moderate levels of maternal antibody. A dose response study with Vaxsafe® IBD was undertaken to measure the response of broilers to 3 dose levels of Vaxsafe® IBD in the presence of IBD maternal antibody. It was possible to demonstrate that doses lower than the minimum end-of-shelf-life titre ($10^{2.4}$ EID₅₀) of the vaccine stimulated active antibody levels that would be protective of under Australian and overseas field conditions (Table 3). These data confirmed that Vaxsafe® IBD would protect against Australian immunosuppressive virus strains and overseas virulent strains.

Figure 1. Mean group titres at 7, 14, 21 and 28 days post vaccination with Vaxsafe® IBD

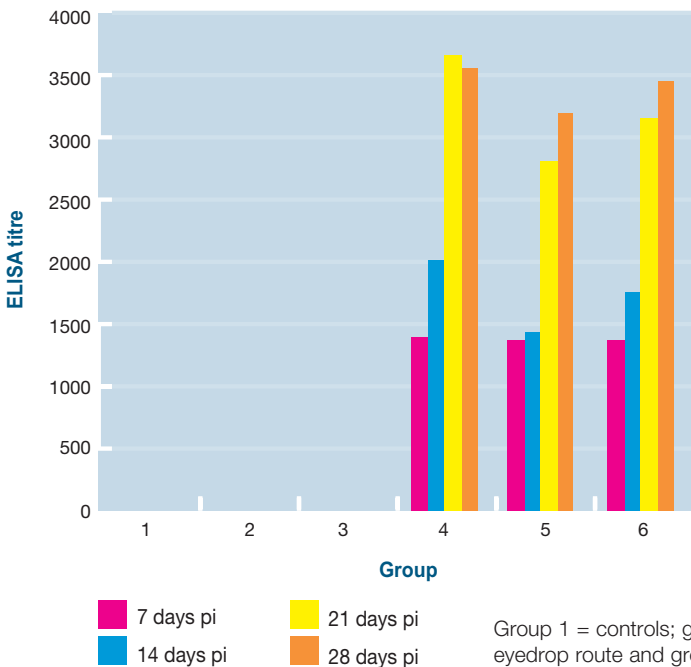


Table 3. IBD antibody response of broiler chickens derived from a single donor flock vaccinated with three dose levels of Vaxsafe® IBD in the presence of IBD maternal antibody

Vaccine virus dose (log ₁₀ EID ₅₀)	# broiler chicks	Age at Vacc. (days)	IBD ELISA (IDEXX) GMT			
			Average age in days			
			15	25	32	37
2.7	48800	15	130	306	1167	1099
2.4*	48000	16	78	743	637	876
2.2	66000	12	182	40	373	ND**

* Vaccine minimum end-of-shelf-life titre

** ND = Not Determined

Group 1 = controls; groups 2 to 5 = doses of 0.1, 1.1, 2.1 and 3.7 EID₅₀ by eyedrop route and group 6 = 2.1 EID₅₀ by the oral route

Productivity Benefits

Vaccination with Vaxsafe® IBD confers major productivity benefits particularly in respect of reduction in broiler mortality. Evidence also suggests a slight improvement in the performance index factor (PIF) (Table 2).

Vaccine Use

A full description of the storage, handling and method of administration of Vaxsafe® IBD is described in the product leaflet that accompanies the vaccine.

Vaccine Presentation

Vaxsafe® IBD is supplied as a freeze-dried product in 1000 and 2000 doses presentations in a 10 mL glass vial with a rubber stopper and tear-off aluminium cap.

Vaccine Administration

Vaxsafe® IBD must be prepared for administration in drinking water in the manner described in the leaflet which accompanies the product.

Vaccine Storage

Vaxsafe® IBD should be held at -18°C or lower, if the full shelf-life of three years is to be achieved.

Vaccination Program

Birds should be vaccinated once from 14 days of age. The precise day of vaccination should be calculated to optimise the response of birds in the presence of IBD maternal antibody. The correct day for vaccination should be determined by calculating the mean IBD IDEXX ELISA antibody titres of a sample of chickens prior to vaccination. The correct procedure to achieve best results is explained in the product leaflet.



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