



Vaxsafe[®] MG

(Strain ts-11)



FOR ANIMAL TREATMENT ONLY
Vaxsafe[®] MG
(Strain ts-11)
1000
doses
For eye
Application
READ THE
ENCLOSED
LEAFLET
BEFORE USE
BIOPROPERTIES



BIOPROPERTIES
The Vaccine Innovators

Features of Vaxsafe® MG (Strain ts-11)

- Single dose for life-long protection
- Safe for poultry
- Prevents vertical transmission of *Mycoplasma gallisepticum* (MG)
- Vaccine can be monitored using RSA and ELISA serology
- Improves broiler performance and egg production.



Safety Studies

Pathogenicity

Vaxsafe® MG (Strain ts-11) has been shown to be apathogenic in chickens. A study was undertaken to evaluate the pathogenicity of Vaxsafe® MG, in comparison to wild type MG by intra-air sac inoculation of 2 week old chicks. No gross lesions were observed in the trachea or air sacs of any Vaxsafe® MG vaccinated chickens at 2 weeks post inoculation, whereas such lesions developed in most birds exposed to wild type MG (Table 1). Further, Vaxsafe® MG could not be isolated from the air sacs of any of the vaccinated chickens, however it was readily isolated from the air sacs of wild-type inoculated birds.

Effect of vaccine overdosing

Chickens were exposed to a 10 times overdose of Vaxsafe® MG. No clinical signs of respiratory disease were observed in any of the treatment groups.

Bird to bird transmission of vaccine organism

Vaxsafe® MG transmits poorly to chickens in close contact (laterally), and will not transmit to physically separated birds. It is therefore effective when used in MG eradication programs. Vaxsafe® MG does not persist in the air sacs after vaccination and is therefore not transmitted vertically. This was clearly demonstrated in a field study involving 200,000 broiler breeder chickens and their progeny. In this study no evidence of vertical transmission was detected. This experiment also demonstrated that Vaxsafe® MG will block vertical transmission of wild-type MG.

Reversion to Virulence

Vaxsafe® MG has been shown not to increase in pathogenicity following rapid passage in chickens or Mycoplasma medium.

Table 1. Pathogenicity of Vaxsafe® MG: effect of intra – air sac inoculation into young chickens.

Treatment	Serology (RSA)*	Air sac lesions**	MG isolation	
			Air sac	Trachea/Nasal sinus
Wild-type	3/5	4/5 (2.8)	4/5	8/10
Vaxsafe® MG	0/5	0/5 (0.0)	0/5	4/10
Mycoplasma broth	0/5	0/5 (0.0)	0/5	0/10

* rapid serum agglutination test

** number affected / number examined (mean score)

Vaccine Administration

A full description of the method of storage, handling and administration of Vaxsafe® MG (Strain ts-11) is described in the product leaflet that accompanies the vaccine.

Vaccine Presentation

Vaxsafe® MG (Strain ts-11) is supplied in a plastic peel-top 30mL eyedropper bottle with a rubber stopper and aluminium seal. Each bottle is supplied with a dropper teat and contains 1000 doses.

Vaccine Administration

Thaw each bottle in a 35°C water bath. Remove the aluminium seal and stopper and insert the dropper teat. A full dose should be administered in a single drop to the eye of each bird. A blue dye can be added to the vaccine to check the accuracy of administration.

Vaccine Storage

The vaccine is supplied frozen (on dry-ice) and should be held at –70°C or lower if the full shelf-life of four years is to be achieved. However, the vaccine will maintain its potency for up to 4 weeks, if held in a freezer at –20°C

Vaccination program

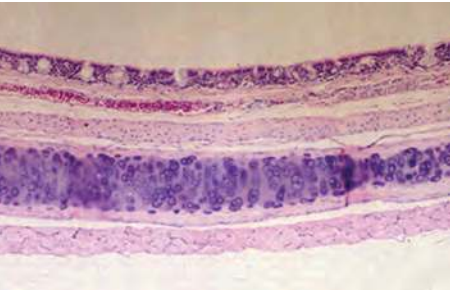
Only MG-free flocks should be vaccinated. Birds should be vaccinated once between 4 and 6 weeks of age. Birds should not be moved into an MG infected area until at least 3 weeks after vaccination. Vaccination of flocks in which antibiotics are being used (especially those with anti-mycoplasma activity) must be avoided. Where antibiotics have been used, allow for a period of drug withdrawal as prescribed for the antibiotic before vaccinating with Vaxsafe® MG. Vaxsafe® MG can be co-administered with other live respiratory vaccines, including Vaxsafe® MG .

Product Development

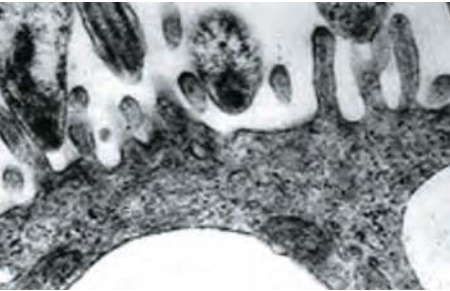
Vaxsafe® MG (Strain ts-11) is a live attenuated (temperature sensitive) vaccine for the control of chronic respiratory disease (CRD) caused by *Mycoplasma gallisepticum* (MG) in chickens. The technology was developed at the University of Melbourne and licensed to BIOPROPERTIES Pty Ltd in 1989. The original MG field isolate was attenuated by chemical mutation and then selected for preferential growth at a lower temperature (33°C) compared to the core chicken body temperature (39°C). The temperature sensitive clone selected for vaccine development was identified as Strain ts-11.

A seed lot system was developed to ensure uniformity of production batches and following proof of safety and efficacy, the product was registered in Australia in 1996. The finished product, containing a suspension of live MG Strain ts-11 organisms in mycoplasma medium, is presented in plastic bottles each containing 1,000 doses. An eyedropper tip is provided for vaccine administration. Safety and efficacy have been confirmed by a number of laboratory scale and field use studies.

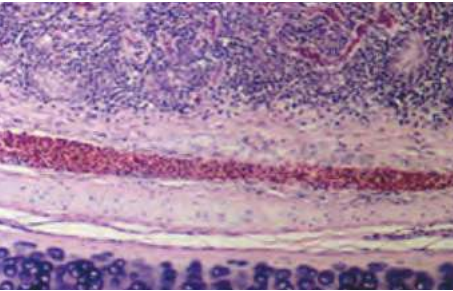
Cross section of normal trachea



MG attached to tracheal mucosa



Tracheal lining thickened by virulent MG



Efficacy Studies

Protection

Vaxsafe® MG has been shown to protect chickens from clinical disease induced by challenge with pathogenic field strains of MG (Table 2). Although antibody responses (RSA) were lower to Vaxsafe® MG than to an inactivated vaccine, the level of protection, as measured by reduced thickening of tracheal mucosa after challenge, was much higher. Vaxsafe® MG has also been shown to block vertical transmission of wild-type MG in commercial broiler breeder chickens.

Onset of immunity

Following vaccination with Vaxsafe® MG, peak levels of immunity are obtained within 3-4 weeks. Flocks should therefore be vaccinated at least 3 weeks prior to moving to a high-challenge environment.

Duration of immunity

Laboratory studies have demonstrated that Vaxsafe® MG persists on the mucosal surfaces of the upper respiratory tract of the bird and provides ongoing antigenic stimulation. This mechanism is the basis for the superior protection achieved following Vaxsafe® MG compared with that following the administration of an inactivated MG vaccine (Table 2).

Serology

A serum antibody response following vaccination with Vaxsafe® MG can be measured using the RSA and the ELISA test systems. Measurement of the antibody response allows assessment of the vaccine 'take' and enables distinction from the antibody response to wild-type MG, the latter inducing high levels (4+) of antibody soon after exposure.

Table 2. Local Immunity in Airways: Aerosol challenge with virulent (Appin) field strain of MG: comparison of Vaxsafe® MG and an inactivated MG vaccine.

Group	n	Mean RSA Score^	Thickness of tracheal mucosa (_m)
Vaxsafe®MG*	10	1.8 (1.1)	71.4 ^b
MG Bacterin*	10	3.7 (0.5)	251.1 ^c
Unvaccinated* and challenged	10	0	253.6 ^c
Not vaccinated or challenged	10	0	44.3 ^a

* aerosol challenge with virulent (Appin) field strain of MG

^ mean rapid serum agglutination test serology score 0-4 (sd)

a b c p>0.05

Productivity Benefits

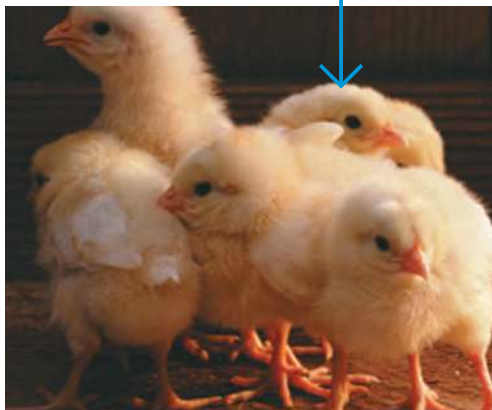
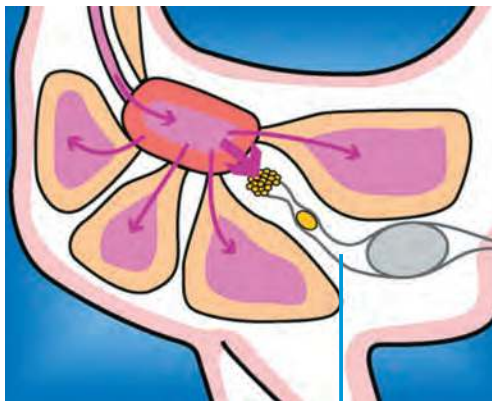
Breeder and broiler performance

Vaxsafe® MG confers productivity benefits in the performance of breeders and their broiler progeny in the field. Marked improvement in feed conversion rates (FCR) and a decrease in broiler mortality* have been demonstrated following vaccination of breeders with Vaxsafe® MG (Table 3).

Table 3. Improved broiler performance after vaccination of commercial meat breeders with Vaxsafe® MG.

Breeder Trial Groups	Isolation rate of MG from embryos	Broiler performance	
		FCR	Mortality
Vaxsafe® MG	0	2.05	5.3%
Unvaccinated	42%	2.44	10.7%

* Barbour *et al* (2000) Poultry Science 79:1730 - 1735



Vaxsafe®MG prevents vertical transmission of virulent MG

Egg production

Significant improvements in egg production have been observed in layer flocks following the use of Vaxsafe® MG. Field trials in Australia indicated an increase in hen day egg production of up to 10 eggs in vaccinated flocks when compared with unvaccinated flocks. A trial in Japan demonstrated an increase following vaccination with Vaxsafe® MG of approximately 23 eggs per hen housed (HH) (7.3%), up to 76 weeks of age when compared with birds vaccinated with an inactivated MG vaccine (Table 4).

Table 4. Improved Egg Production in Commercial layers in Japan*

Trial Groups	Mean HH eggs to 76 weeks
MG-BAC (Solvay)	315.3
Vaxsafe®MG	338.4

* Data courtesy Nippon Biologicals Inc

Field experience in the USA and Australia indicated that Vaxsafe® MG has no detrimental effect on egg production or on egg quality (including shell and contents).

References and further reading

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Registered Office/Distribution
36 Charter Street, Ringwood
VIC 3134 AUSTRALIA

T +61 3 9876 0567
F +61 3 9876 0556
www.bioproperties.com.au

Manufacturing Division
11-15 Moores Road, Glenorie
NSW 2157 AUSTRALIA

T +61 2 9652 0087
F +61 2 9652 0914