

FOR ANIMAL TREATMENT ONLY

Vaxsafe® ST Vaccine (living)

Active Constituent: Each dose contains $\geq 10^{7.0}$ CFU* living, attenuated *aroA* deletion *Salmonella* Typhimurium Strain STM-1

* Colony Forming Units

Statement of Claims: An aid in the control of shedding and colonisation in chickens and adult fowls by *S. Typhimurium* and *S. Infantis*. The vaccine has been shown to reduce the excretion of virulent *S. Typhimurium* and provide chickens with an aid in protection against challenge by this strain to at least 45 weeks of age. The vaccine has been shown to reduce the excretion of virulent *S. Infantis* and provide chickens with an aid in protection against challenge by this strain to at least 65 weeks of age. The vaccine can also provide protection against some other strains of *Salmonella*.

Strain STM-1 was generated from a naturally occurring Australian wild type of *S. Typhimurium* isolated from a chicken and attenuated by deletion of the *aroA* gene. This rendered the organism vitamin dependant (aromatic amine) and non-virulent, but retentive of the ability to induce a protective immune response in the bird.

Colonisation of poultry flocks by pathogenic strains of *S. Typhimurium* with subsequent contamination of meat and eggs is a major cause of salmonellosis in man and can be detrimental to the health of the bird. This vaccine was not determined to be a genetically modified organism by the Australian Office of the Gene Technology Regulator.

**1000 / 2000 / 3000 / 4000 /
5000 / 10 000 Doses**

Contents:

A freeze-dried plug containing at least 1000 / 2000 / 3000 / 4000 / 5000 / 10 000 doses.

READ DIRECTIONS CAREFULLY

DIRECTIONS FOR USE:

Contraindications:

- This product is contraindicated for vaccinating unhealthy birds.
- Administration by IM injection is contraindicated in birds less than 12 weeks of age.

Precautions:

- Time of administration: early morning administration is recommended to allow minimum stress to the flock.
- Exposure to disease must be minimised as much as possible, especially during the first two weeks after vaccination.
- Avoid stressful conditions during the first two weeks after vaccination.

Side effects:

- Mild transient clinical signs such as inactivity or hunched posture may be noted in some birds following vaccination.
- Intramuscular administration of Vaxsafe ST may result in clinical signs related to endotoxemia which may start approximately 24 hours after vaccination and continue for up to 48 hours.

- This vaccination may cause swelling at the site of injection. This generally resolves within 28 days of vaccination and does not require specific treatment.

Dosage and Administration:

- For use in susceptible day-old chickens by coarse spray immediately upon placement, followed by a booster in the drinking water at 14 days of age.
- For protection of older fowls the vaccination program as described for younger chickens must be followed up with further vaccinations in the drinking water (such as 6 weeks of age) followed by intramuscular injection of the vaccine at 12 weeks of age.
- Vaccine is administered to birds by intramuscular injection into either the left or right pectoral muscle. The volume to be administered by intramuscular injection must be set at 0.5 mL.
- Vaxsafe ST may be administered at the same time as inactivated NDV and EDS vaccines.

GENERAL INSTRUCTIONS:

Vaccine may be administered by coarse spray to day old chickens, followed by administration at 14 days of age through the drinking water using a Medication tank or directly dispensing into the drinking founts. Intramuscular injection is best given into one of the pectoral muscles.

- The use of sterile equipment and proper sterile technique is critical to avoid contamination of Vaxsafe ST.
- Vaccine must be held at between 4 and 30°C prior to use.
- Reconstituted vaccine must not be frozen.
- Vaccine must be used within 4 hours of reconstitution. Discard unused vaccine after this period.
- Administer only as directed.
- Vaccinate all birds in a flock at one time.
- Administer a full dose to each bird.
- Use entire contents of vial when first opened.
- Good husbandry practise and careful attention to techniques of administration are required.

Coarse Spray Method:

- Reconstitute the vaccine by injecting distilled water in to the vaccine vial using a sterile syringe and needle.
- The freeze dried plug should rapidly dissolve.
- Remove the resuspended vaccine from the vial.
- The vaccine should be administered to birds according to the spray vaccine unit manufacturer's instructions. The spray unit should be designed to deliver droplets of approximately 100 microns diameter (coarse spray).
- The spray unit should have been flushed, cleaned and sterilized at the end of the previous days use using boiling water and a non-residual disinfectant. Parts that come in contact with the vaccine should be removed where possible and boiled or autoclaved.
- Reassemble the vaccination unit and fill the vaccine container with distilled water. The quantity of water depends on the capacity of the vaccine container, number of chicks to be vaccinated, or maximum number of chicks that can be vaccinated in two hours; whichever is limiting.
- Add the required doses of resuspended vaccine to distilled water in the spray unit's vaccine container.
- The vaccine container should be kept cool during spraying.
- Before spraying chicks an empty box should be sprayed by the unit to check that all parts of the box are covered by the spray and that the unit is properly primed.
- Once spraying commences, the chicks should be checked for wetness from the spray around the head and face. Spraying should extend to all chickens in the box including those in the corners.
- Ensure that boxes are only sprayed once.
- Ensure that the box remains in the spray unit long enough to receive a full spray dose.
- Avoid variations in spray pressure as these can alter droplet size.
- Use skim milk powder at the rate described below if potable tap water rather than distilled water is used.

Medication Tank Method

- Do not administer any medication or disinfectants in the drinking water within two (2) hours prior to or following vaccination.
- Determine the drinking water consumption of the chickens over a 2 hour period on the day of vaccination.
- On the morning of the vaccination, turn off the main water supply and thoroughly clean all drinking fonts. Do not use disinfectants during cleaning.
- The Medication tank should be emptied and cleaned. Do not use disinfectants during cleaning.
- Fill the Medication tank with a sufficient amount of water calculated to last the chickens for two hours of water consumption. Add skim milk powder at the rate of 2.5 gm/L and mix this thoroughly with the fresh water in the tank.
- Add the previously prepared vaccine into the tank and again mix thoroughly.
- Turn on the Medication tank and drain off any clear water until the water containing the skim milk powder and vaccine appears as a cloudy white colour.
- Continue to encourage consumption of all the vaccine/water over the next two hours.
- Turn on the main water supply only after all the vaccine mixture has been consumed.

Directly into Drinking Fonts:

- As described above, determine the water consumption of the chickens over two hours.
- Turn off the main water supply and then clean, rinse and empty the water troughs.
- Avoid the use of disinfectants or detergents during cleaning.
- Prepare the vaccine initially in a one-litre volume as described above.
- Prepare a larger volume of water (eg in a clean plastic garbage bin) equivalent to the volume of water that the birds will consume over a two hour period. Add skim milk powder at the rate of 2.5 gm/L and mix thoroughly.
- Mix in the previously prepared vaccine and thoroughly stir the mixture.
- Distribute the vaccine mixture with a clean container to all the drinking fonts.
- Encourage the birds to drink and ensure the fonts continue to be topped until all the vaccine/water is consumed.
- The vaccine/water should be consumed within two hours.
- Ensure that all the chickens only have access to the vaccine/water and not to any other water supplied during this two hour period.

Preparation of Vaccine for Intramuscular Injection:

- Calculate the total number of vaccine doses required based on the total bird number rounded to the nearest whole value.
- The vaccine is supplied as a freeze dried plug in a vial. This must be reconstituted before use.
- Use sterile needles, syringes and other equipment to avoid contamination of the product.
- Reconstitute the vaccine by removing at least 3 mL of vaccine diluent from the vaccine diluent pack using a sterile syringe and needle and injecting the diluent into the vial of vaccine.
- Gently inject through the vaccine vial stopper, shake and then create a small vacuum; allow the contents of the vial to be drawn into the syringe.
- Remove all the suspended vaccine from the vial with the syringe and inject the contents into the vaccine diluent bag (or bags, as appropriate).
- Ensure all vaccine is removed from the vial. Rinse the vial with a further 3 mL or more of diluent if necessary.
- Shake the diluent pack(s) thoroughly but gently to mix the vaccine and the diluent.
- Each 1000 dose vial of vaccine (or equivalent) will require a 500 mL pack of sterile diluent.
- Two 1000 dose vials can be reconstituted into a 1000 mL pack of sterile diluent. If only a single 1000 dose vial is to be reconstituted, using a syringe and needle, accurately

reconstitute the freeze dried vaccine and add this to a 500 mL pack of diluent.

- Sterile diluent for vaccine preparation and administration is available in separate packs sizes for reconstitution of Vaxsafe ST.

Intramuscular Injection:

- Vaccine is administered to birds by intramuscular injection into either the left or right pectoral muscle.

WITHHOLDING PERIOD: Do not administer later than 14 days before slaughter for human consumption.

USER SAFETY INFORMATION:

If the vaccine is accidentally splashed into the operator's eyes, the eyes and face should be thoroughly washed with water to avoid any potential reaction.

Additional information is available in the product Safety Data Sheet.

FIRST AID:

If poisoning occurs, contact a Doctor or Poisons Information Centre on 13 11 26.

STORAGE INSTRUCTIONS:

Store below -18°C (Deep Freeze). Protect from light. The vaccine must be used prior to the expiry date marked on the label.

DISPOSAL:

Discarded ampoules/containers should immediately be placed in a designated and appropriately labelled 'biologicals' container. If this option is not available, bury the ampoule/container below 50 cm in a disposal pit specifically marked and set up for this purpose clear of waterways, desirable vegetation and roots. Discarded needles/sharps should immediately be placed in a designated and appropriately labelled 'sharps' container.

CAUTION:

The capability of this vaccine to produce satisfactory results depends upon many factors including, but not limited to, conditions of storage and handling by the user, administration of the vaccine, health and responsiveness of individual chickens and degree of field exposure. Therefore, directions for use should be followed carefully.

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WARRANTY AND DISCLAIMER

Vaxsafe® ST has been tested and meets safety and potency standards according to the Standards required by the APVMA. BIOPROPERTIES Pty Ltd accepts no responsibility for events arising from the misuse or mishandling of the product. BIOPROPERTIES Pty Ltd gives no warranty (express or implied) with respect to the product, including without limitation any warranty as to completeness, merchantability or fitness for a particular purpose. Under no circumstances shall BIOPROPERTIES Pty Ltd be liable for indirect, special, consequential or punitive damages.

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