

FOR ANIMAL TREATMENT ONLY

Vaxsafe® SBH Vaccine (living)

Active Constituents: Each dose contains ≥ 1428 pfu*, Marek's Disease Virus (MDV) Strain SB-1 (serotype 2) and ≥ 1466 pfu, Herpesvirus of Turkeys (HVT) Strain FC126 (serotype 3), living, cell-associated.
*plaque forming units

Statement of Claims: For the prevention of clinical Marek's disease in chickens.

The vaccine viruses have been purified and grown in tissue culture derived from specific pathogen free (SPF) embryos.

2000 / 3000 / 4000 Doses

Contents: The product consists of one glass ampoule of vaccine and a plastic container of diluent. Each ampoule of vaccine contains a minimum of 2000, 3000 or 4000 doses of vaccine. Ampoules will be contained on canes within cardboard sleeves. Diluent packs are supplied in 200, 400, 600, 800 and 1200 mL bags which are stored at room temperature.

READ SAFETY DIRECTIONS BEFORE OPENING OR USING

This vaccine is recommended for use in healthy one-day-old chickens and for *in ovo* vaccination of 18-day-old embryonated eggs. It is essential that the chickens are maintained under good environmental conditions and that exposure to field virus is reduced as much as possible.

DIRECTIONS FOR USE:

DO NOT USE in chickens if the parent flock has been vaccinated with this vaccine or another bivalent Marek's Disease vaccine.

Contraindications:

- This product is contraindicated for vaccinating unhealthy chickens or contaminated embryonated eggs.
- *In ovo* vaccination should be avoided on eggs with high surface bacterial/ fungal contamination, or in an environment with high bacterial/ fungal contamination. Bacterial/ fungal contamination will induce embryo mortality, reduce hatch rate and result in unthrifty chickens when placed into the field.

Precautions:

- Do NOT use diluent packs that have changed colour (yellow) or become cloudy in appearance.
- Administer only as directed and use entire contents within 1 hour after thawing.
- Vaccinate all chickens or embryonated eggs at one time.
- Administer a full dose to each chicken or embryonated egg.
- Avoid stress conditions during and following vaccination.
- Use entire contents when first opened.
- Exposure to Marek's Disease Virus after placement must be minimised, especially during the first two weeks of life.
- Avoid carcass damage by carefully following instructions under 'Method of Vaccination'.

Dosage and Administration:

The vaccine may be given to day-old chickens by subcutaneous inoculation or given by *in ovo* vaccination to 18-day-old chicken eggs using an egg injection system *

Preparation of vaccine for use:

Read the full instructions and follow them exactly.

- Know and follow all precautions and safety practices before handling liquid nitrogen.

- Vaccine ampoules are shipped in a vessel that has been pre-treated with liquid nitrogen. The transport vessel does NOT contain free liquid nitrogen, but holds the vaccine below -150°C . Vaccine must be removed from the transport vessel IMMEDIATELY upon arrival and into an on-site storage vessel that contains liquid nitrogen. Vaccine transfer must be carried out as a direct transfer from the transport vessel into the on-site storage vessel. DO NOT EXPOSE VACCINE TO ROOM TEMPERATURE FOR MORE THAN 10 SECONDS. Each canister must be at -196°C AT THE TIME OF TRANSFER of the canes. If cardboard sleeves are present on the vaccine canes, they should be left in place until immediately prior to use. One cane per canister is shipped inverted. Vaccine in the tip of inverted ampoules may indicate thawing during transit. Contact Bioproperties IMMEDIATELY if this occurs.
- Before withdrawing vaccine from liquid nitrogen, protect hands with leather gloves, wear long sleeves and protect face and eyes with a plastic face shield or wear protective goggles. Ampoules that have been cracked during manufacture or transportation may explode.
- Mix vaccine in a well-ventilated clean room. Disinfect work station with alcohol prior to vaccine preparation. Prepare diluent pack by wiping the rubber stoppers with an alcohol swab.
- Match diluent pack with vaccine according to the following instructions: For subcutaneous inoculation of day-old chickens, where the dose volume is 0.2 mL, 200 mL of diluent is required for each 1000 doses. For *in ovo* application of vaccine, where the dose volume has been set at 0.05 mL per egg, 4000 doses must be added per 200 mL diluent pack. For *in ovo* application of vaccine, where the dose volume has been set at 0.1 mL per egg, 2000 doses must be added per 200 mL diluent pack. Diluent must be at room temperature ($22 - 25^{\circ}\text{C}$) prior to adding vaccine.
- Prepare syringe (10 mL) and needle (18G x 37 mm) using aseptic technique. Add 3 mL of diluent to the syringe and replace cap or leave inserted into the port of the diluent pack.
- Remove from the liquid nitrogen only the ampoules that are going to be used immediately. (NOTE: remove ampoules in descending order from each cane; only raise the aluminium cane to the neck of the canister to ensure remaining ampoules are not exposed to room temperature). Ampoules removed from liquid nitrogen for more than 30 seconds must not be returned to the liquid nitrogen container as loss of potency will occur.
- Ampoules must be thawed QUICKLY (60 – 70 sec). Place up to two (2) ampoules in a large vessel containing 5–10 L of clean freshly-prepared water. The water temperature must be maintained between 27°C and 29°C using a thermostatically controlled heating element and monitored using a certified thermometer. Remove gloves, collect the ampoules quickly and agitate gently during thawing to minimise thaw time. Avoid inverting ampoules which prevents vaccine entering lids. When the contents have thawed, remove ampoules from the thaw bath and wipe dry with clean paper towel. Remove the lids carefully within the towel by rotating toward the operator. (CAUTION): fine glass pieces may be generated during lid removal so ensure eye protection is in place and ampoule lids are removed within the paper towel. The broken surface of lid and ampoule are sharp and should not be touched with fingers or paper to avoid cutting and contamination, respectively.
- Add approximately 1 mL of diluent to the open ampoule before inserting the needle to the bottom of the ampoule and SLOWLY withdrawing ampoule contents (Note: it is essential that the vaccine be withdrawn slowly from the ampoule to minimise damage to the delicate cells contained within the vaccine. Cell destruction reduces vaccine potency).
- SLOWLY expel contents into the diluent bottle through the rubber stopper of the diluent bag. Gently rock the bag during ejection. Withdraw a further 3 mL of diluent and gently rinse the inside of each ampoule from the top down. Eject the rinse back into the diluent bag slowly. Withdraw a further 1 mL of diluent into the syringe and eject immediately to rinse the syringe. Thoroughly mix the prepared vaccine by gently rocking the diluent bag back-and-forth at least 5-6 times.
- The vaccine may be used at room temperature or chilled in an ice bath before and/ or during use. Ensure all the

vaccine is used within 1 hour after preparation. Agitate the vaccine every 10 minutes to maintain a uniform suspension of the cells.

- Use the vaccine/diluent mixture as described below.

Method of Vaccination:

(a) Subcutaneous vaccination of day old chickens

- **IMPORTANT:** Sterilise vaccinating equipment by autoclaving for a minimum of 15 minutes at 121°C, or boiling in water for at least 20 minutes. NEVER allow chemical disinfectants to come in contact with vaccinating equipment.
- Vaccination may be undertaken with a hand-gun syringe or with an automatic vaccinator.
- A sterile automatic syringe should be fitted with a 20 gauge, 25 mm needle that is set to accurately deliver 0.2 mL per dose. Check the accuracy of delivery several times during the vaccination procedure. Keep needles sharp and clean by replacing them frequently (approximately every 1000 chickens).
- Automatic vaccinators should be correctly disinfected, assembled and calibrated prior to the commencement of vaccine preparation. Pressure gauges, triggers, vaccine flow and operation should be monitored throughout vaccination.
- Maintain cleanliness at all times.
- Dilute the vaccine only as directed, observing all precautions and warnings for handling.
- Keep the bottle of diluted vaccine in an ice bath if the room temperature exceeds 27°C and agitate frequently (every 10 minutes) during use.
- If vaccinating by handgun, inject chickens under the loose skin at the back of the neck (subcutaneously), holding the chicken by the back of the neck just below the head. The loose skin in this area is raised by gently pinching with the thumb and forefinger. Insert the needle beneath the skin in a direction away from the head. Inject 0.2 mL per chicken. Avoid hitting the muscles and bones in the neck.
- Maintain accuracy rather than speed. Staff using automatic syringes should not exceed 1500 chickens per hour. Staff using automatic vaccinators should not exceed 2500 chickens per hour otherwise chickens may be missed.
- Use the entire contents of vaccine container within one hour after mixing the vaccine with the diluent.

(b) In ovo vaccination

- Prepare vaccine as described above
- Ensure embryos have been incubated for 18-19 days at the time of inoculation.
- Carefully read and follow the egg injection system* operator's manual before commencing vaccination. Failure to follow instructions for the egg injection system operation may result in personal injury, embryonic morbidity and mortality.
- Sanitise the egg injection system before and after use in accordance with the procedures described in the operator's manual.
- Inject 0.05 mL dose into each embryonated egg. Refer to the operator's manual supplied with the egg injection system for the correct operation.
- Egg injection systems are routinely serviced by the manufacturer and must be maintained according to the manufacturers recommendations
- Ensure chemical disinfectants used on the egg injection system are of the highest quality and meet the minimum active concentration levels recommended by the manufacturer.

WITHHOLDING PERIOD: NIL

USER SAFETY INFORMATION

Liquid nitrogen precautions:

Only properly trained personnel should handle the liquid nitrogen containers and vaccines. These persons should be familiar with AS 1894 - Code of Practice for The Safe Handling of Cryogenic Fluids and the Dangerous Goods (Storage and Handling) Regulations 1989 (S.R. No. 323/1989). Liquid nitrogen is extremely cold. Accidental contact with the skin or eyes can cause severe frostbite. Protect eyes with goggles or face shield. Wear leather gloves and long sleeves when removing and handling frozen ampoules or when adding liquid nitrogen to the container. Storage and handling of liquid nitrogen containers

must be in a well-ventilated area. Excessive amounts of nitrogen reduce the concentration of oxygen in the air of an unventilated space and can cause asphyxiation.

Before withdrawing vaccine from liquid nitrogen, protect hands with leather gloves, wear long sleeves and protect face and eyes with a plastic face shield or wear protective goggles. Ampoules that have been cracked during manufacture or transportation may explode after removal from liquid nitrogen.

FIRST AID:

Liquid Nitrogen

- If drowsiness occurs, get to fresh air quickly and ventilate the entire area.
- If a person becomes groggy or loses consciousness while working with liquid nitrogen, get the person to a well-ventilated area immediately.
- If breathing has stopped, begin artificial respiration. Call a physician immediately.

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

STORAGE INSTRUCTIONS:

KEEP OUT OF REACH OF CHILDREN

Ampoules: Store in liquid nitrogen container.

Diluent: Store at or below room temperature (DO NOT freeze).

Diluent MUST be at room temperature at the time of use.

Liquid nitrogen container: Carefully observe all liquid nitrogen precautions including wearing eye protection and leather gloves. Store in a cool, well-ventilated area. Check liquid nitrogen level daily. Keep container away from incubator intakes and chicken boxes.

DISPOSAL:

Discarded containers should immediately be placed in a designated and appropriately labelled "Biologicals" container. If this option is not available, bury the containers below 500 mm in a disposal pit specifically marked and set up for this purpose clear of waterways, desirable vegetation and roots.

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.

CONTACT DETAILS:

BIOPROPERTIES Pty Ltd
ACN 007 303 728
36 Charter Street
Ringwood
Victoria 3134, Australia
PH: 03 9876 0567 FAX: 03 9876 0556



WARRANTY AND DISCLAIMER

Vaxsafe® SBH (Strains SB-1 and FC126) 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

[*eg. INOVOJECT® is an example and is a registered trademark of EMBREX Inc.]

APVMA No: 63411/0909

Code/Version No: LFT-SBH V7