

## FOR ANIMAL TREATMENT ONLY

# Vaxsafe<sup>®</sup> HVT Vaccine (living)

**Active Constituents:** Each dose contains  $\geq$  8000 pfu\* living Herpesvirus of Turkeys Virus (HVT) strain FC 126 (serotype 3).  
\*plaque forming units

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

The vaccine virus has been purified and grown in tissue cultures derived from specific pathogen free (SPF) embryos.

## 1000 / 2000 Doses

**Contents:** The product consists of one glass ampoule of vaccine and a glass or plastic container of diluent. Each ampoule of vaccine contains a minimum of 1000 doses of vaccine. Ampoules containing 2000 doses are on canes within cardboard sleeves. For subcutaneous inoculation of day-old birds, where the dose volume is 0.2 mL, 200 mL of diluent is provided for each 1000 doses. For *in-ovo* application of vaccine, where the dose volume has been set at 0.1 mL per egg, 200 mL diluent is supplied for each 2000 doses of vaccine. The glass ampoule is transported and maintained in liquid nitrogen [approx. -196°C]. The diluent is maintained at room temperature.

### READ DIRECTIONS CAREFULLY

This vaccine is recommended for use in healthy one-day-old chickens and for *in ovo* vaccination of 18 to 19 day old embryonated eggs. It is essential that the birds are maintained under good environmental conditions and that exposure to disease causing viruses is reduced as much as possible.

### DIRECTIONS FOR USE:

#### Contraindications:

- This product is contraindicated for vaccinating unhealthy birds or contaminated embryonated eggs.

#### Precautions:

- Administer only as directed and use entire contents when first opened.
- Vaccinate all birds or embryonated eggs at one time.
- Administer a full dose to each bird or embryonated egg.
- Avoid stress conditions during and following vaccination.
- Use entire contents when first opened.
- Exposure to disease must be minimised as much as possible 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 birds by subcutaneous inoculation or given by *in ovo* vaccination to 18-19 day-old chicken eggs using the EMBREX INOVOJECT<sup>®</sup> 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.

- 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.
- 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.
- 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 to be thawed at the rate of 200 mL per 1000 doses of vaccine. Diluent must be at room temperature (22 – 25°C) prior to use.
- Prepare syringe (10 mL) and needle (18G x 37 mm) using aseptic technique. Add 3 mL of diluent to the syringe and replace cap.
- 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 should be used for vaccine and must not be returned to the liquid nitrogen container, as loss of titre will occur.
- Ampoules must be thawed QUICKLY (60 – 70 sec). Place up to two (2) ampoules in a large container containing 5 – 10L of clean freshly-prepared water. The water temperature must be maintained between 27 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 avoids 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 the lids away from the operator. (CAUTION): fine glass pieces may be generated during lids 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.
- 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 placed into an ice bath during use. Ensure all the vaccine is used within 1 hour after preparation. Agitate the vaccine every 10 minutes to ensure a uniform suspension of the cells.
- Use the vaccine/diluent mixture as described below.

## Method Of Vaccination:

### (a) Subcutaneous vaccination of day old birds

- **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.
- Give subcutaneously only.
- 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 birds).
- 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.
- Inject birds under the loose skin at the back of the neck (subcutaneously), holding the bird 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 bird. Avoid hitting the muscles and bones in the neck.
- Maintain accuracy rather than speed. Staff using automatic syringes should not exceed 1500 birds per hour. Staff using automatic vaccinators should not exceed 3000 birds per hour otherwise birds may be missed.
- Use the entire contents of vaccine container within one hour after mixing the vaccine with the diluent.

### (b) In-ovo vaccination

- Carefully read and follow the INOVOJECT<sup>®</sup> operator's manual before commencing vaccination. Failure to follow instructions for INOVOJECT<sup>®</sup> operations may result in personal injury, embryonic morbidity and mortality.
- Sanitise the INOVOJECT<sup>®</sup> Egg Injection System before and after use in accordance with the procedures described in the INOVOJECT<sup>®</sup> operator's manual.
- Inject 0.1 mL dose into each embryonated egg. Refer to the operator's manual supplied by EMBREX Inc for the correct operation of the INOVOJECT<sup>®</sup> Egg Injection System.

[NB. INOVOJECT<sup>®</sup> is a registered trademark of EMBREX Inc.]

## WITHHOLDING PERIODS: NIL

## USER SAFETY INFORMATION:

Additional information is available on the Material Safety Data Sheet.

### 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 gaseous

nitrogen reduces the concentration of oxygen in the air of an unventilated space and can cause asphyxiation.

## 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 13 11 26

## STORAGE INSTRUCTIONS:

**Ampoules:** Store in liquid nitrogen container.

**Diluent:** Store at room temperature.

**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 bird boxes.

## DISPOSAL:

Discard unused vaccine and empty vaccine bottles into a disinfectant solution (e.g. chlorine based bleach). Dispose of any such inactivated, unused vaccine and empty containers by wrapping in paper and putting in garbage.

In cases of spillage, soak up the liquid with an absorbent sponge or cloth and incinerate. Treat the surface with a disinfectant solution (e.g. chlorine based bleach).

## 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 birds and degree of field exposure. Therefore, directions for use should be followed carefully.

## CONTACT DETAILS:

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## WARRANTY AND DISCLAIMER

Vaxsafe<sup>®</sup> HVT 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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