SAFETY DATA SHEET

COMBAVAC 3 IN 1 LIVE TICK FEVER VACCINE CONCENTRATE

SECTION 1 IDENTIFICATION

Product Name: **COMBAVAC 3 IN 1** LIVE TICK FEVER VACCINE **(Concentrate)**

Other Names: Trivalent frozen vaccine concentrate

Manufacturer's Product Code: CON/3I1

Recommended use: For control of tick fever (Bovine babesiosis and anaplasmosis) by vaccination in cattle.

Details of manufacturer:
Department of Agriculture and Fisheries
Biosecurity Queensland
Tick Fever Centre
280 Grindle Road, Wacol Queensland 4076 Australia

Emergency phone number:
Telephone: +61 7 3898 9655
Fax: +61 7 3898 9685
E-mail: tfc@daf.qld.gov.au
Web-site: www.biosecurity.qld.gov.au (search for 'tick fever')

SECTION 2 HAZARDS IDENTIFICATION

Hazard classification –product: Non-Hazardous ad Non-Dangerous Material

Storage and transport in cryogenic liquid:
UN Hazard Classes Division 2.2- Non–flammable non-toxic gas

Poisons schedule Number: Not scheduled

SECTION 3 COMPOSITION AND INFORMATION ON INGREDIENTS

Vaccine Concentrate

Ingredients	**CAS No**	**Concentration**
Bovine blood containing live attenuated *Babesia bovis, Babesia bigemina and Anaplasma centrale* organisms.	Not set	50%
Heparin	9005-49-6	2.5 units/ml (approx)
Streptomycin sulphate	3810-74-0	0.5 mg/ml
Benzylpenicillin sodium	69-57-8	500 iu/ml
Glycerol	56-81-5	11%
Buffered saline diluent	Not set	to 100%

SAFETY DATA SHEET

COMBAVAC 3 IN 1 LIVE TICK FEVER VACCINE CONCENTRATE

Reconstituted Vaccine

Ingredients	**CAS No**	**Concentration**
Bovine blood containing live attenuated *Babesia bovis, Babesia bigemina and Anaplasma centrale* organisms.	Not set	4.5%
Heparin	9005-49-6	0.5 units/ml (approx)
Streptomycin sulphate	3810-74-0	0.5 mg/ml
Benzylpenicillin sodium	69-57-8	500 iu/ml
Glycerol	56-81-5	11%
Buffered saline diluent	Not set	to 100%

This is a commercial biological product whose exact ratio of components varies. Minor quantities of other non-hazardous ingredients (basic salts) are included within the saline diluent.

SECTION 4 FIRST AID MEASURES

WARNING: You should seek medical advice if accidental self-injection occurs

Self injection: Accidental self-injection may lead to an inflammatory response and medical advice should be sought on the management of deep injections, particularly those near a joint or associated with bruising. If possible the application of gentle squeezing pressure with absorbent material (e.g. facial tissues) at the injection site will swab up unabsorbed vaccine. Strong squeezing of the site should be avoided. The damaged area should be thoroughly cleansed and a topical antiseptic applied.

Swallowed: If in mouth, thoroughly wash mouth with water, and then give some water to drink. Further measures should not be necessary.

Eye: If this product comes into contact with eyes, hold open and wash well with clean running water. Ensure irrigation under eyelids by occasionally lifting them. Do not try to remove contact lenses unless trained.

Skin: If this product comes into contact with skin, wash skin with soap and water.

Advice to Doctor: Accidental self injection may lead to an inflammatory response and deep injections, particularly those near a joint or associated with bruising should be treated medically or surgically. The vaccine contains low levels of the antibiotics Benzylpenicillin and Streptomycin sulphate as preservatives (approximately 500 units of

benzylpenicillin and 0.5 mg streptomycin sulphate per mL of vaccine).

There is no convincing evidence that the organisms used in the vaccine (*Babesia bovis, Babesia bigemina and Anaplasma centrale*) are infective for humans. However related organisms present overseas including *Babesia microti* and *Babesia divergens* have been shown to be able to infect and cause disease especially in elderly and immune compromised individuals. The organisms are intra-erythrocytic parasites and the disease syndrome can resemble malaria. More information on the zoonotic disease seen in the United States can be found on the website http://www.cdc.gov/parasites/babesiosis/

SECTION 5 FIRE FIGHTING MEASURES

Core information: Non-Flammable and Non-Explosive Material

Hazchem Code: None allocated

SECTION 6 ACCIDENTAL RELEASE MEASURES

Core information: No specific advice on containment is required.
Vaccine spill can be flushed with water or cleaned with wipes and disposed into general rubbish bin.

SECTION 7 HANDLING AND STORAGE

Condition of storage
Vaccine concentrate: Store Combavac 3 in 1 live tick fever vaccine concentrate in liquid nitrogen at -196^{0}C

Ventilation: Always handle and store liquid nitrogen in well ventilated areas.

When using this product, the main danger is from the liquid nitrogen normally used to preserve the product. If liquid nitrogen contacts any skin or tissue, severe frost bite will occur. Read label and SDS for instructions in the handling of frozen material, and of liquid nitrogen For more information consult AS 1894-1997 'The storage and handling of non-flammable cryogenic and refrigerated liquids"

Reconstituted vaccine: Store reconstituted Combavac 3 in 1vaccine at 2º to 8º C
Refrigerate, do not freeze and protect from direct sunlight.
Dispose of unused reconstituted vaccine after 8 hours after thawing/reconstitution.

SAFETY DATA SHEET

COMBAVAC 3 IN 1 LIVE TICK FEVER VACCINE CONCENTRATE

SECTION 8 EXPOSURE CONTROL/PERSONAL PROTECTION

Personal protective equipment:

For vaccine use: None required

For liquid Nitrogen: Use personal protective equipment when handling liquid nitrogen:

1. Goggles, safety glasses or face shield for face and eye protection
2. Clean, **dry** leather or PVC gloves
3. Clean and **dry** protective clothing and safety shoes

For more information consult AS 1894-1997 "The storage and handling of non- flammable cryogenic and refrigerated liquids".

SECTION 9 PHISICAL AND CHEMICAL PROPERTIES

Appearance: Liquid blood based vaccine deep red in colour, cryopreserved in 5 mL polypropylene cryotubes

Odour: Odourless

Boiling Point: No data

Vapour Pressure: No data

Specific Gravity: Approximately 1.01

SECTION 10 STABILITY AND REACTIVITY

Core information: This product is stable for at least 10 years under defined storage conditions of -196ºC liquid nitrogen.
The reconsitutued vaccine has a shelf life of just 8 hours and should be discarded after this time.

SECTION 11 TOXICOLOGICAL INFORMATION

No specific data are available for the product for chronic exposure symptoms. The vaccine is non-toxic and the live organisms contained in the vaccine are believed to be harmless to humans.
However the following people may be at increased risk after self-injection:

- elderly people
- people with weakened immune systems e.g. people whose

immune system has been altered by diseases such as leukaemia or lymphoma, or through drugs and radiation, or who are HIV or AIDS sufferers
- people whose spleen has been removed.

Acute Swallowing, skin contact, eye contact or inhalation: This product is handled correctly, there is currently no known danger to humans. The product contains low levels of Benzylpenicillin and Streptomycin sulphate antibiotics and individuals allergic to these antibiotics should avoid self-injection or ingestion.

SECTION 12 ECOLOGICAL INFORMATION

Ecotoxicity: No evidence

This product is biodegradable. It will not accumulate in soil or water or cause long term problems.

SECTION 13 DISPOSAL CONSIDERATIONS

Dispose of unused/expired product, containers and outer packaging in the garbage or by incineration. Discarded needles should be placed in a designated and appropriately labelled 'sharps' container. The container should be of a type to reduce the possibility of injury to handlers during collection and disposal. Incineration is the preferred method of disposal, otherwise 'sharps' should be buried at a suitable site, such as an on-farm chemical disposal pit located away from watercourses.

SECTION 14 TRANSPORT INFORMATION

UN Number (product): None allocated

UN Number (transport): UN 1977, Nitrogen, refrigerated liquid

Dangerous Goods Class and Subsidiary Risk - product None allocated, no subsidiary risk

Dangerous Goods transport packaging: IATA Packing Instruction 202

Special precautions for user: Concentrate 3 in 1 Live tick fever vaccine must be transported in liquid nitrogen transport tank

SAFETY DATA SHEET

COMBAVAC 3 IN 1 LIVE TICK FEVER VACCINE CONCENTRATE

SECTION 15 REGULATORY INFORMATION

Regulatory status:

The vaccine is registered with the Australian Pesticides and Veterinary Medicines Authority (APVMA)
The vaccine is not classified as hazardous according to the criteria of Safe Work Australia.
It is not Dangerous Good according to the Australian Dangerous Goods (ADG) Code

SECTION 16 OTHER INFORMATION

This SDS has been prepared on 15/09/16 in accordance to the National Code of Practice for Preparation of Safety Data Sheets for hazardous chemicals by Safe Work Australia - February 2016.