THERION BIOLOGICS

MATERIAL SAFETY DATA SHEET

SECTION 1 – IDENTIFICATION OF PRODUCT AND COMPANY

Therion Biologics Corporation
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Telephone 617-876-7779
Hours of Operation Monday through Friday, 8:30 a.m. – 5:00 p.m. (Eastern Standard Time)

Product name Fowlpox Virus Vector

Description Fowlpox virus with or without inserted foreign gene(s)

SECTION 2 - COMPOSITION

Ingredient	Amount
Live fowlpox virus of the Avipoxvirus family	No Greater than 10^{10} pfu/vial

Note: This product contains phosphate buffer, saline, and glycerol at levels considered normal for pharmaceutical formulations. Traces of residual contaminants (such as egg albumin, nucleic acids, fetal bovine serum components from the viral manufacturing process) may be present. The contaminants are controlled to the level required for Investigational New Drugs.

SECTION 3 – HAZARDS IDENTIFICATION

General Fowlpox virus is classified as a Biosafety Level 1 organism. It can infect but does not replicate in humans. It has been used in numerous clinical studies to treat cancer patients. The parental fowlpox virus was derived from an avian vaccine for the prevention of pox virus infection in chickens. Fowlpox virus is infectious for birds.

Eye effects None known.

Skin effects None known.

Inhalation effects None known.

Ingestion effects None known.

Other potential health effects None known.

Route of entry Accidental injection

SECTION 4 – FIRST AID MEASURES

Skin In case of contact, skin should be cleaned with a standard hand-washing detergent.

Eyes In the case of contact, flush eyes with water for 15 minutes and seek medical advice.

Inhalation	None. Estimate dose of exposure and seek medical advice.
Ingestion	None. Estimate dose of exposure and seek medical advice.

SECTION 5 – FIRE FIGHTING MEASURES

General hazard	This product is a nonflammable aqueous solution and will not support combustion.

SECTION 6 – ACCIDENTAL RELEASE MEASURES

General	Review sections 3, 8 and 11 before proceeding with clean up
Accidental Release	Contain the source of the spill or leak. Use absorbent material to absorb liquid from contaminated surface. Dispose of absorbent materials in biohazard bags, review section 13. Clean contaminated surface with detergent based cleaners or 10% Clorox. Dispose of cleaning materials in biohazard bags. Individuals involved in clean up should wear protective clothing including gloves, eye protection and laboratory coat.

SECTION 7 – HANDLING AND STORAGE

General handling	Aseptic loading of vaccine from sealed vaccine vials into appropriate syringes can be performed in standard clinical facilities.
Storage conditions	Vaccine should be stored at -70°C or colder.

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

Facilities	Handling of sealed vaccine vials and loading of syringes for administration of vaccine by injection may be conducted in standard clinical facilities.
Respiratory protection	None required
Eye protection	Eye protection is recommended during handling to prevent accidental contact.
Skin protection	No special protective clothing is required. Standard laboratory or clinical smock is recommended.
Hand protection	Vaccine should be handled using impervious gloves to prevent accidental skin exposure

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Physical form	Frozen
Color	Cloudy white to gray

SECTION 10 – STABILITY AND REACTIVITY

Reactivity	Fowlpox viruses are non-reactive with nonliving materials.
Conditions to avoid	Avoid dilution of vaccine with materials other than those noted in the clinical protocol. Unapproved diluents may result in significant loss of titer. Do not store at room temperature. Avoid storage of undiluted vaccine at 2°C - 8°C for longer than 4 days.
Stability	Stable at -70°C or colder. Ongoing stability studies will be conducted.
Hazardous decomposition products	None known

SECTION 11 – TOXICOLOGY INFORMATION

Toxicology summary	
Murine Neurovirulence	Fowlpox viruses are not neurovirulent in standard murine neurovirulence assays
Murine Multiple Dose Studies	Studies in mice with fowlpox viruses have not resulted in significant adverse effects
Nonhuman Primate Safety Studies	Studies with rhesus monkeys have not resulted in significant adverse effects.
Clinical Studies	Over 200 humans have been vaccinated with Therion's fowlpox viruses by either intradermal, subcutaneous, intramuscular, or intravenous routes. Intravenous doses up to 6×10^9 virus plaque forming units have been administered. No serious systemic adverse events have been observed.
Reproductive Studies	No reproductive studies have been performed.

SECTION 12 – ECOLOGICAL INFORMATION

Environmental overview	This material is considered to be a biohazard and as such release to the environment should be avoided.

SECTION 13 – DISPOSAL INFORMATION

Disposal procedure	Observe all local and federal regulations regarding disposal of hazardous biological waste. Store materials in appropriate biohazard containers prior to disposal.

SECTION 14 – TRANSPORTATION INFORMATION

General shipping instructions	Fowlpox virus must be shipped according to all state and federal regulations as a biological product for investigational use.

SECTION 15– OTHER

Date prepared	May 26, 2004
Prepared by	Therion Biologics Corporation

Although the information, opinions and recommendations contained in this Material Safety Data Sheet are compiled from sources believed to be reliable, Therion accepts no responsibility for the accuracy, sufficiency, or reliability for any loss or injury resulting from the use of the information. Newly discovered hazards are frequent and this information may not be completely up to date.