Cultures of replication defective lentiviral vectors are non-infectious and are not hazardous materials as defined by OSHA 1919.1200. However, these materials are produced in cells where there is the possibility of recombination to form wild type virus. As such, they should be handled as potentially infectious material.

**Description:**
Lentiviral vectors consist of recombinant transgene sequences (e.g., marker or human genes), and viral packaging and regulatory sequences which are then flanked by lentiviral long terminal repeats (LTRs). The removal of the viral structural genes renders the vector replication defective and dependent upon a helper vector(s) or packaging cell line. Lentiviruses are enveloped viruses and upon leaving the producer cell line, the viral capsid becomes enclosed in a lipid by layer derived from the host cell. The vectors’ LTRs are self-inactivating (SIN), thus restricting mRNA production from integrating vectors to the internal promoter, severely reducing full-length vector transcripts. By default, the lentiviral vectors are pseudotyped with the VSV-G Indiana envelope serotype; however the envelope protein can be customized as desired.

Lentiviral cultures are provided as either low concentration (>1x10^6 infectious units/ml) virus in tissue culture media, or as high concentration, purified (>1x10^9 infectious units/ml) virus in phosphate buffered saline. Trace components present in the purified virus include, but are not limited to, inorganic salts, vitamins and other nutrients, and human cellular proteins, carbohydrates, amino acids, and fats. The material is normally shipped and stored frozen. Further vector application and handling is described in the following publication:


**SECTION I**
**Hazardous Ingredients**
None

**SECTION II**
**Physical Data**
Liquid or frozen particle suspensions
SECTION III
Health Hazards
Replication-defective lentiviral vectors are not known to cause any diseases in humans or animals. However, lentiviruses can integrate into the host cell genome and thus pose some risk of insertional mutagenesis.

SECTION IV
Fire and Explosion
None

SECTION V
Reactivity
Not chemically reactive. Will enter permissive mammalian cells and interact or react with cellular components.

SECTION VI
Method of Disposal
Spill: Contain spill and decontaminate the area using a disinfectant such as chlorine bleach (10% f.c.), Wescodyne, or detergent-based disinfectant.

Waste Disposal: Dispose of viral stocks by autoclaving at 121°C for 30-45 minutes. Dispose of infected liquid cultures by decontamination with chlorine bleach (10% f.c.) for 10 minutes and then dispose of in sink. Dispose of infected animal carcasses or tissues by incineration.

Follow all Federal, State, and Local regulations.

SECTION VII
Special Protective Information
Handle as biohazardous material under Biosafety Level 2 containment.
SECTION VIII
Special Precautions or Comments

The Gene Therapy Center recommends that all Lentiviral vectors and cultures be handled by qualified microbiologists using appropriate safety procedures and precautions. Upon accidental exposure to Lentiviral vectors, seroconversion towards HIV-1 viral proteins could result and health provider should be contacted. Detailed discussions of laboratory safety procedures are provided in Laboratory Safety: Principles and Practice (Fleming et al., ASM Press, Washington D.C., 1995), and in the U.S. Government Publication, Biosafety in Microbiological and Biomedical Laboratories (CDC, 1999). This and other publications are available at the Centers for Disease Control Office of Health and Safety’s website at http://www.cdc.gov/od/ohs/biosfty/bmb14/bmb14toc.htm

Information on the classification of human etiologic agents on the basis of hazard can be found as Appendix B in the NIH Guidelines for Research Involving Recombinant DNA Molecules at http://www.grants.nih.gov/grants/policy/recombinantdnaguidelines.htm

The above information is accurate to the best of our knowledge. All materials and mixtures may present unknown hazards and should be used with caution. The user should exercise independent judgment as to the hazards based on all sources of information available. The Gene Therapy Center shall not be held liable for any damage resulting from the handling or use of the above product.