

EMERGENCY TELEPHONES: 301-251-6638 or 1-800-485-5808

Cultures of replication-defective AAV vectors are non-infectious and are not hazardous materials as defined by OSHA 1919.1200. The vectors may be used under biosafety level (BSL)-1 conditions, however they are generated under BSL-2 conditions due to the use of cells during the production process where there is a possibility of recombination to form wild-type virus. As such, they should be handled as potentially infectious material.

Description

AAV vectors consist of recombinant transgene sequences (e.g., marker or human genes) flanked by the AAV inverted terminal repeats. The removal of the majority of viral structural genes renders the vector replication-defective and dependent on an AAV helper virus. AAV cultures are normally provided as purified viral particles in phosphate buffered saline (PBS) at a concentration of up to 1×10^{13} GC/ml. The viral stock consists of particles containing the vector genome (full capsids) and a variable number of empty viral capsids in PBS. Other trace components present 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.

SECTION I

Hazardous Ingredients

None

SECTION II

Physical Data

Liquid or frozen particle suspensions

SECTION III

Health Hazards

Replication-deficient AAV cultures are not known to cause any diseases in humans or animals

SECTION IV

Fire and Explosion

None

SECTION V

Stability and Reactivity

Stable. Will enter mammalian cells in the presence of adenovirus (or other helper virus) and wild-type AAV can integrate into host cell DNA.

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 stock 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

Recombinant AAV (all serotypes) constructs, in which the transgene does not encode either a potentially tumorigenic gene product or a toxin molecule and are produced in the absence of a helper virus can be handled in BSL-1 facility. Otherwise it should be handled as biohazardous material under BSL-2 containment.

SECTION VIII

Special Precautions or Comments

Vigene Biosciences, Inc. recommends that all AAV vectors and cultures be handled by qualified biologists using appropriate safety procedures and precautions. Detailed discussions of laboratory safety procedures are provided in **Laboratory Safety: Principles and Practice** (Fleming et al., ASM Press, 2009), and in the U.S. Government Publication, **Biosafety in Microbiological and Biomedical Laboratories** (CDC, 2009). This and other publications are available at the Centers for Disease Control Office of Health and Safety's website at <https://www.cdc.gov/biosafety/publications/index.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 or Synthetic Nucleic Acid Molecules** at https://osp.od.nih.gov/wp-content/uploads/2013/06/NIH_Guidelines.pdf

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. Vigene Biosciences, Inc. shall not be held liable for any damage resulting from the handling or use of the above product.

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