

**SAFETY DATA SHEET (SDS)****Replication-Defective Recombinant Adeno-Associated Virus (rAAV) Vectors****SECTION I – IDENTIFICATION**

Product Identifier:

Name: Replication-defective recombinant adeno-associated virus
Synonym or Cross Reference: rAAV, AAV, AAV vector
Characteristics: Parvovirus, non-enveloped, 20-26 nm diameter, linear DNA genome

Packaging Company Information:

Virovek, Inc.
8300 Cypress Creek Pkwy., Ste. 100
Houston, TX 77070
Tel: (346) 569-5012
info@virovek.com | www.virovek.com
In case of medical emergency, call 911.

Recommended Use: Use for laboratory research purposes

SECTION II – HAZARD IDENTIFICATION

Hazard Classification: Our AAV vectors are not hazardous materials as defined by OSHA 1919.1200 and cannot be classified according to the Globally Harmonized System (GHS) of classification and labeling.¹

Hazard Statements: In accordance with NIH Guidelines for AAV vectors not encoding harmful genes, this product may be used under Biosafety Level 1 (BSL-1) guidelines.^{2,3}

Precautionary Statements: We recommend that qualified, trained biologists use this product. See **Section VII** and **VIII** for proper handling guidelines.

Description:

AAV is a parvovirus that will enter mammalian cells and remain in episomal form in non-dividing cells. It exhibits no pathogenic symptoms in humans, elicits no immune response in humans, and has been used in clinical trials for gene therapy and/or approved for market use by the FDA. Wild-type AAV integrates stably at human chromosome 19. Our product consists of recombinant, replication-defective AAV vectors, with *rep* and *Cap* genes for replication removed. Our AAV is generated with insect-specific baculovirus as a helper virus, instead of other human pathogens such as adenovirus or herpes simplex virus (HSV).⁴ Therefore, residual remains of adenovirus, or HSV will not be present in our product. Every customer that we serve is required to disclose the contents of their gene sequences. We do not package carcinogenic sequences, or genomes of bloodborne pathogens such as HIV, HBV, HCV, and other potentially infectious materials (OPIM).



SECTION III – COMPOSITION

- Ingredients:
 - rAAV < 1%
 - Phosphate-buffered saline (PBS)* > 99%
 - Pluronic F-68 0.001%

**in the case that a different buffer is specified by the customer for a specific product, the aforementioned buffer will replace PBS in this composition.*
- Hazardous Ingredients: None
- Physical Data: Aqueous particle suspension
- Health Hazards: rAAV is not known to cause disease in humans or animals
- Fire and Explosion: Not flammable
- Reactivity: Stable; not reactive.
- Special Protective Information: BSL-1 PPE. See **Section VIII**.

SECTION IV – FIRST-AID MEASURES

No symptoms are anticipated after exposure. We recommend following precautionary practices:

- Skin Contact: If the exposure draws blood, wash and scrub thoroughly for at least 5 minutes with soap and warm running water. If the exposure does not draw blood, wash and scrub for at least 1 minute. Seek medical attention if symptoms persist. Inform medical professional of exposure.
- Eye Exposure: Rinse with eyewash for at least 5 minutes. Seek medical attention if symptoms persist. Inform medical professional of exposure.
- Inhalation: In case of exposure to aerosols, move affected individual to fresh air. Give oxygen if individual has difficulty breathing.
- Ingestion: Do not induce vomiting. Immediately seek medical attention or call Poison Control Center.

SECTION V – FIRE-FIGHTING MEASURES

AAV vectors do not pose a flammability risk. Viral particles are suspended in a non-flammable liquid. High heat will deactivate AAV.

SECTION VI – ACCIDENTAL RELEASE MEASURES

In case of an indoor or outdoor spill, isolate and soak up the liquid with paper towels. If the spill is outside a biological safety cabinet, avoid breathing in aerosols. Disinfect area with 10% bleach (1% sodium hypochlorite) or detergent-based disinfectant to deactivate virus, and let stand for 10 minutes. Discard soaked materials into proper biohazardous waste, or autoclave them. See **Section XIII, Disposal Considerations**.



SECTION VII – HANDLING, STORAGE, AND DISPOSAL

Safe Handling Practices

Practice BSL-1 Practices: Wash hands after use, minimize splashes and aerosol formation, label properly, and avoid eating or drinking while using this product.² Alcohols are not effective disinfectants for AAV; use 10% bleach to decontaminate lab surfaces. See Disposal Considerations and **Section VIII** for details. Local biosafety information may be available.

Storage Considerations

AAV is stable at room temperature and 4°C. It may be thawed at room temperature or in a 37°C water bath. Store at -80°C to preserve long-term biological integrity, and do not store at -20°C. After 5 years at -80°C, AAV generally loses viability in long-term storage. For best quality, please avoid unnecessary freeze-thawing of AAV vectors, as excessive cycles may result in decrease in titer and loss of biological activity.⁴

SECTION VIII – PERSONAL PROTECTION / EXPOSURE CONTROLS

Personal Protection: General BSL-1 Dress Recommendations. Full-length laboratory coat, disposable nitrile gloves, safety glasses, closed-toe shoes.

Exposure Controls: For practices that may produce aerosols, recommended engineering controls include mechanical ventilation (i.e. use of biological safety cabinets).

SECTION IX – PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance (physical state, color, etc.):** colorless liquid particle suspension
- **Upper/lower flammability or explosive limits:** N/A
- **Odor:** odorless
- **Vapor pressure:** N/A
- **Odor threshold:** N/A
- **Vapor density:** N/A
- **pH:** 7.0-7.6
- **Relative density:** N/A
- **Melting point/freezing point:** N/A
- **Solubility:** N/A
- **Initial boiling point and boiling range:** N/A
- **Flash point:** N/A
- **Evaporation rate:** N/A
- **Flammability (solid, gas):** Not flammable



- **Partition coefficient: n-octanol/water:** N/A
- **Auto-ignition temperature:** N/A
- **Decomposition temperature:** N/A
- **Viscosity:** N/A

SECTION X – STABILITY AND REACTIVITY

AAV vectors are very chemically stable. They are recommended for use at room temperature (~23°C), as they are biologically stable at this temperature.

SECTION XI – TOXICOLOGICAL INFORMATION

- **Possible Routes of Exposure:** Inhalation, ingestion, eye contact, skin contact/bloodstream
- **Symptoms:** No anticipated incubation period or symptoms
- **Measures of Toxicity:** N/A
- **Carcinogenicity:** This product is not listed in the NTP, IARC or OSHA database for carcinogenicity.

SECTION XII – ECOLOGICAL INFORMATION

- **Toxicity:** N/A
- **Persistence and Degradability:** Inherently biodegradable
- **Bioaccumulation:** Does not bio-accumulate
- **Mobility in Soil:** N/A
- **Results of PBT and vPvB Assessment:** PBT/vPvB assessment not available as chemical safety assessment not required/not conducted
- **Other Adverse Effects:** N/A

SECTION XIII – DISPOSAL CONSIDERATIONS

See the following options:

- 1) Dispose of in labeled “Biohazardous Waste” to be picked up by licensed disposal company
- 2) Autoclave at 125°C for a minimum of 30 minutes before regular trash disposal
- 3) For solutions, add 10% bleach (1% sodium hypochlorite) and let sit for 10 minutes to disinfect and deactivate mixture before drain disposal.

SECTION XIV – TRANSPORT INFORMATION

- **UN/NA Number:** 3245
- **UN/NA Proper Shipping Name:** Inherently biodegradable



- **Transport Hazard Class:** Non-hazardous for Transport
IATA: Not dangerous goods
DOT (US): Not dangerous goods
IMDG: Not dangerous goods

SECTION XV – REGULATORY INFORMATION

United States Regulatory Information:

- **SARA 313:** This product is regulated by SARA
- **Clean Air Act, Sec. 112 Hazardous Air Pollutants (HAPs):** This product does not contain HAPs
- **California Proposition 65:** This product does not contain chemicals listed under Proposition 65
- **WHMIS Hazard Class:** Non-controlled

Europe Regulatory Information:

- **RoHS:** This product does not contain chemicals listed under RoHS
- **REACH:** This product does not contain chemicals listed under REACH

SECTION XVI – INFORMATION SOURCES

1. Occupational Safety and Health Administration (OSHA) 1910.1200. Hazard Communication. https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=standards&p_id=10099
2. Section IV - Laboratory Biosafety Level Criteria. https://www.cdc.gov/biosafety/publications/bmb15/bmb15_sect_iv.pdf
3. NIH Guidelines for Research involving Recombinant or Synthetic Nucleic Acid Molecules. https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html.
4. Min Chen, MD, CEO. <https://www.virovek.com/aav-system/#SafetyStorage>

To the best of our knowledge, the information provided is accurate. The user of this product must take responsibility to determine the proper handling and disposal requirements in accordance to regional and federal regulations, and to best protect the health and safety of all persons who come in contact with this product. Virovek shall not held liable for any damage or injury that results from handling or use of the above product.

Date Last Revised: January 17th, 2023