

Pipeline and Hazardous Materials Safety Administration 1200 New Jersey Avenue, SE Washington, DC 20590

DOT-SP 21493 (FIRST REVISION)

EXPIRATION DATE: 2029-02-28

(FOR RENEWAL, SEE 49 CFR 107.109)

1. <u>GRANTEE</u>: K&M Transportation Services, LLC d.b.a. GenVault Transport Services

Dover, DE

2. PURPOSE AND LIMITATION:

- a. This special permit authorizes the transportation in commerce of certain Division 6.2 infectious substances and biological substances in alternative packagings (freezers) in a dedicated motor vehicle by highway. This special permit provides no relief from the Hazardous Materials Regulations (HMR) other than as specifically stated herein. The most recent revision supersedes all previous revisions.
- b. The safety analyses performed in the development of this special permit only considered the hazards and risks associated with the transportation in commerce.
- c. No party status will be granted to this special permit.
- 3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.
- 4. <u>REGULATIONS FROM WHICH EXEMPTED</u>: 49 CFR § 173.196(a) and 173.199(a) in that alternate packagings are authorized as specified herein, and 178.603 and 178.609(d) in that the drop tests are waived.
- 5. <u>BASIS</u>: This special permit is based on the application of K&M Transportation Services, LLC dated November 22, 2024, submitted in accordance with § 107.105.

Tracking Number: 2024115373

6. HAZARDOUS MATERIALS (49 CFR 172.101):

Hazardous Materials Description			
Proper Shipping Name	Hazard Class/ Division	Identi- fication Number	Packing Group
Biological substance, Category B	6.2	UN3373	N/A
Infectious substances, affecting animals only	6.2	UN2900	N/A
Infectious substances, affecting humans*	6.2	UN2814	N/A

^{*}Infectious substances for which effective treatments and preventative measures are not usually available are not allowed under this special permit.

7. SAFETY CONTROL MEASURES:

a. PACKAGING:

- (1) Infectious substances and biological substances, as listed in Paragraph 6. of this special permit, must be packed as follows:
 - (i) Primary receptacle: Materials must be packed in securely sealed watertight vials with a capacity not exceeding 10 ml. Vials must be capable of withstanding cryogenic storage;
 - (ii) Secondary packaging: Closed stainless steel boxes, containing the primary receptacles secured in individual cells by separators. Stainless steel boxes shall be further packed in a heat-sealed, watertight plastic bag and, secured to stainless steel racks. No more than 13 boxes shall be on each rack; and
 - (iii) Outer packaging: Large capacity, commercial-grade, double-walled, stainless steel, liquid nitrogen-cooled freezers (MVE Model 1800HE-series freezer or Taylor Wharton Model LABS 80K freezer) containing the racks. Racks must be secured in the freezer to prevent tipping or shifting. Sufficient absorbent material must be placed in the freezer to serve as dunnage and to absorb the entire contents of all primary receptacles.
 - (iv) Total volume of hazardous material shall not exceed 100 L per outer packaging.

- (v) Outer packagings must be tightly closed, strapped around the doors, and secured against movement in the transport vehicle.
- (vi) A single shipment is limited to eight (8) freezers per transport vehicle.
- (2) The substances within the outer packaging must be kept frozen within the freezer operating temperature range for the duration of transportation.
- (3) A back-up freezer system and sufficient liquid nitrogen to keep the substances within the operating temperature range for at least twice the estimated travel time must be carried on the transport vehicle.
- (4) The liquid nitrogen supply tank and all outer packagings must be secured against movement in the transport vehicle.

b. OPERATIONAL CONTROLS:

- (1) This special permit authorizes the transport of packages containing infectious substances and biological substances using a specially-designed, dedicated transport vehicle.
- (2) Packages must be prepared, transported, and unpacked by trained employees of K & M Transportation Services, LLC (d.b.a. GenVault Transport Services).
- (3) Not more than one transport vehicle may be operated at any time.
- (4) An itemized list of contents must be securely attached to the outside of each outer packaging.
- (5) Emergency refrigeration and response equipment and procedures must be in place and operation to address loss of refrigeration, delay in transportation, or release of an infectious substance
- (6) When transporting infectious materials described in § 172.800(b)(13), a security plan conforming with § 172.800 must be in place.
- (7) The Department of Transportation must be notified no fewer than five (5) business days prior to each move indicating the date of the move, the quantity of material to be moved, the origin and destination of the move, the route of transport, any arrangements with appropriate governmental agencies, and any other safety measures.

8. <u>SPECIAL PROVISIONS</u>:

- a. A person who is not a holder of this special permit who receives a package covered by this special permit may reoffer it for transportation provided no modification or change is made to the package or its contents and it is reoffered for transportation in conformance with this special permit and the HMR.
- b. A current copy of this special permit must be maintained at each facility where the package is offered or reoffered for transportation.
- c. Each outer packaging (freezer) must be marked "DOT-SP 21493" in accordance with § 172.302(c).
- 9. MODES OF TRANSPORTATION AUTHORIZED: Motor vehicle.
- 10. <u>MODAL REQUIREMENTS</u>: A current copy of this special permit must be carried aboard each motor vehicle used to transport packages covered by this special permit.
- 11. <u>COMPLIANCE</u>: Failure by a person to comply with any of the following may result in suspension or revocation of this special permit and penalties prescribed by the Federal hazardous materials transportation law, 49 U.S.C. 5101 <u>et seq</u>:
 - o All terms and conditions prescribed in this special permit and the Hazardous Materials Regulations, 49 CFR Parts 171-180.
 - o Persons operating under the terms of this special permit must comply with the security plan requirement in Subpart I of Part 172 of the HMR, when applicable.
 - o Registration required by § 107.601 et seq., when applicable.

Each "Hazmat employee", as defined in § 171.8, who performs a function subject to this special permit must receive training on the requirements and conditions of this special permit in addition to the training required by §§ 172.700 through 172.704.

No person may use or apply this special permit, including display of its number, when this special permit has expired or is otherwise no longer in effect.

Under Title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) — "The Hazardous Materials Safety and Security Reauthorization Act of 2005" (Pub. L. 109-59), 119 Stat. 1144 (August 10, 2005), amended the Federal hazardous materials transportation law by changing the term "exemption" to "special permit" and authorizes a special permit to be granted up to two years for new special permits and up to four years for renewals.

12. <u>REPORTING REQUIREMENTS</u>: Shipments or operations conducted under this special permit are subject to the Hazardous Materials Incident Reporting requirements specified in 49 CFR §§ 171.15 - Immediate notice of certain hazardous materials incidents, and 171.16 - Detailed hazardous materials incident reports. In addition, the grantee(s) of this special permit must notify the Associate Administrator for Hazardous Materials Safety, in writing, of any incident involving a package, shipment or operation conducted under terms of this special permit.

Issued in Washington, D.C.:

for William Schoonover

Associate Administrator for Hazardous Materials Safety

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Material Safety Administration, U.S. Department of Transportation, East Building PHH-13, 1200 New Jersey Avenue, Southeast, Washington, D.C. 20590.

Copies of this special permit may be obtained by accessing the Hazardous Materials Safety Homepage at https://www.phmsa.dot.gov/approvals-and-permits/hazmat/special-permits-search. Photo reproductions and legible reductions of this special permit are permitted. Any alteration of this special permit is prohibited.

PO: KH